Assessment of the Health Commodity Supply Sector in Rwanda, September 2003

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About RPM Plus

RPM Plus works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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ACRONYMS

AIDS	acquired immunodeficiency syndrome
ALT	alanine aminotransferase
ART	antiretroviral therapy
AST	aspartate aminotransferase
ARV	antiretroviral
AZT	zidovudine
BUFMAR	Bureau des Formations Médicales Agréées du Rwanda
CAMERWA	Centrale d'Achats de Médicaments Essentiels du Rwanda
CHK	Kigali Hospital Center
CHU	University Hospital Center
CPA	Complementary Package of Activities
DOP	Directorate of Pharmacy
DSS	Direction de Soins de Santé
EDL	essential drugs list
FHI	Family Health International
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GLP	good laboratory practices
HIV	human immunodeficiency virus
MAP	Medical Assistance Program
MIS	management information system
MOH	Ministry of Health
MPA	Minimum Package of Activities
MSH	Management Sciences for Health
NACC	National AIDS Control Commission (also CNLS)
NDP	National Drug Policy
NRL	National Reference Laboratories
NVP	nevirapine
OI	opportunistic infection
PEP	postexposure prophylaxis
PEPFAR	Presidential Emergency Plan for AIDS Relief
PHR	Partners in Health Reform
PMTCT	prevention of mother-to-child transmission
PNILT	National Program against Leprosy and Tuberculosis
PNLS	National AIDS Control Programme
QA	quality assurance
QC	quality control
RPM Plus	Rational Pharmaceutical Management Plus [Program]
SOP	standard operating procedure

STG	standard treatment guideline
STI	sexually transmitted infection
TPHA	T. pallidum hemagglutination assay
TRAC	Treatment and Research AIDS Center
USAID	U.S. Agency for International Development
USD	U.S. dollar
VCT	voluntary counseling and testing
WHO	World Health Organization

MAP OF RWANDA

Map No. 3717 Rev. 7 UNITED NATIONS
December 1993 (Colour)

Department of Public Information
Cartographic Section

EXECUTIVE SUMMARY

Introduction

The Rational Pharmaceutical Management Plus (RPM Plus) Program of Management Sciences for Health (MSH), with funding from the U.S. Agency for International Development (USAID)/Rwanda under the Presidential Plan for Prevention of Mother to Child Transmission (PMTCT) of AIDS and the Presidential Emergency Plan for AIDS Relief (PEPFAR), is assisting the Ministry of Health (MOH) of Rwanda and its key local partners to strengthen the capacity of the public health sector for addressing pharmaceutical and laboratory commodity management needs in support of the expansion of HIV/AIDS programs in Rwanda.

The purpose of the assessment was to identify key constraints and challenges and to develop appropriate recommendations for improving commodity management systems in support of the scale-up of HIV/AIDS services. The assessment was conducted in September 2003 with several months of follow-up to analyze the data. The assessment addressed commodity management issues related to pharmacy and laboratory activities, both of which include key elements of a comprehensive HIV/AIDS prevention and treatment program.

The assessment incorporated interviews with key informants from the Ministry MOH, USAID, the parastatal central medical stores of Rwanda (CAMERWA), and the National Reference Laboratories (NRL), among others. Data were collected by surveying pharmaceutical and laboratory services in 49 pharmacies and 36 laboratories in facilities located in 12 provinces and covering all three levels of the health system—from referral hospitals to health centers. Information was obtained on various aspects of the commodity management system, including policy and legal frameworks, selection, procurement, distribution, use, and management support systems (including information systems and human resources). The structured questionnaires and site selection criteria were developed, tested, and adapted in consultation with the Direction de la Pharmacie (Directorate of Pharmacy; DOP) and CAMERWA.

The Pharmaceutical Sector

Key players in the public pharmaceutical sector include the DOP, CAMERWA, district pharmacies, and service pharmacies located in referral hospitals, district hospitals, and health centers. Additional suppliers to the pharmaceutical sector include the Bureau des Formations Médicales Agréées du Rwanda (BUFMAR) and private wholesalers.

Policy and Legal Frameworks

The DOP has the mandate to oversee the public and private pharmaceutical sector, including the development and implementation of the national drug policy, drug registration and regulation (of the pharmaceutical profession and of facilities), and drug information. Primarily as a result of lack of human resources and budget, the DOP has been unable to carry out some key functions,

such as drug registration, quality assurance, regulation of the pharmaceutical profession, and practices and provision of drug information.

Recently, the MOH developed a draft of the National Drug Policy (NDP), although its text is still pending consultation with the World Health Organization (WHO), approval, and publication. Two laws governing the pharmaceutical sector were put in place in 1999 and 2000. However, these laws would benefit from supportive ministerial instructions and directions. The earlier law calls for a National Drug Registration Commission that is yet to be established. An Essential Drugs List (EDL) has been available since 1997 and was updated in 2002. However, no formal procedures are in place to guarantee its periodic review. Standard operating procedures (SOPs) for importing drugs are available, but no local capacity for the quality assurance of drugs is available in Rwanda, although samples are sent abroad for testing by CAMERWA. No guidelines are available for dispensing and counseling.

Standard treatment guidelines (STGs) for the diagnosis, treatment, and care of HIV/AIDS, sexually transmitted infections (STIs), opportunistic infections (OIs), and other diseases have been developed. However, awareness and availability of these guidelines at the facilities is limited. Only 8 percent of surveyed facilities had the correct manuals for their corresponding level of care.

Human Resources

Staff in the pharmaceutical sector consists of pharmacists as well as other health personnel, especially nurses. Rwanda has about 100 pharmacists, mostly employed in the private sector and based in the capital, Kigali. Only 12 pharmacists are employed by the public sector. At the time of the assessment, the DOP had only three pharmacists. At the service delivery level, pharmacists are found only at referral hospitals. Most pharmacy activities are performed by nurses at A2 level. Other cadres such as pharmacy technicians or pharmacy assistants do not exist. More than 25 percent of facilities hire other staff with primary or secondary education to work in their pharmacies. Although the survey did not detect shortage of staff relative to current workload, there is concern that the introduction and eventual scale-up of antiretroviral therapy (ART) services would cause such a shortage.

Less than half of staff reported having been trained in drug procurement, with a similar ratio having received training in rational drug use. Only one-third reported having been trained in storage and stock management, and virtually none reported having been trained in drug management specific to HIV/AIDS. The assessment found that a number of staff who had received training in pharmaceutical management are not necessarily working in pharmacy services where the training was meant to be applied. More than 80 percent of facilities reported perceiving a need for training in drug quantification, procurement, inventory control, and rational drug use. Pharmacy staff at all levels of the system lack access to technical updates and reference materials.

Infrastructure and Equipment

Standards for physical space and organization of pharmacies are developed by the MOH. Although the assessment found building conditions and space allocation to be acceptable in many pharmacies, 56 percent of facilities were found to require physical upgrades. Most of the facilities have at least the minimum storage equipment (shelves, pallets, and cabinets); however, some of this equipment was found to be in poor condition. Lockable cabinets to ensure secure storage of antiretrovirals (ARVs) and controlled drugs were not always available in pharmacies. Functioning refrigerators were found in 73 percent of the sites. Less than half of these pharmacies within surveyed facilities reported having a reliable electricity supply.

Stock Management

Although 86 percent of the surveyed facilities reported using inventory controls, field visits revealed that substantial errors and omissions exist in recording stock data, with, for example, stock balances frequently not being recorded. This finding is attributed not only to lack of training but also to lack of supervision. Controlled drugs are not always stored separately and secured in accordance with standard pharmaceutical practice. Although not a major focus of the assessment, waste management practices were deficient, with only 59 percent of the facilities reporting having a functioning incinerator.

Drug Availability

Among respondents providing information on stock-outs for a list of tracer drugs (25 percent), none of the referral hospitals reported having experienced stock-outs of essential drugs during a 12-month period. Only 37 percent of the facilities reported having experienced shortages among essential drugs. No clear pattern emerged for stock-outs of particular drugs. However, lack of inventory control data and poor record keeping make it difficult to assess the true extent of stock-outs in these health institutions

Quantification

No SOPs were found to exist for quantification. Most facilities (95 percent) reported using historical consumption data for the quantification process, with only 14 percent using morbidity data. Although 41 percent of facilities also suggested that stock-outs are taken into consideration when calculating orders, it is clear that the quantification process is hampered by lack of reliable data. Most facilities reported that quantification is done by the person in charge of the pharmacy. In many instances, quantification is largely influenced by availability of funds. Only in some facilities (11 percent) is cross-checking of required quantities done using an additional quantification method. Most staff would benefit from training on quantification methods.

Selection

Rwanda updated its EDL in 2002. Although all facilities surveyed reported selecting drugs from the EDL, just 61 percent of the facilities reported limiting their drug selection to the EDL. This

finding should be viewed in the context that only 76 percent of the facilities were found to have a copy of the EDL available.

Financing

All facilities have a cost-recovery system in place. Most of these facilities (67 percent) aim at 100 percent cost-recovery for pharmaceutical services. Two-thirds of referral hospitals keep a separate budget for ARVs. Some pharmaceutical sites have independent financial management and use a special bank account. In half of the facilities, pharmaceutical revenues are used for expenditures other than replenishing drugs, such as salaries. The assessment found that external audits are infrequently conducted at these pharmacies and that price-setting for products sold in the pharmacy is somewhat arbitrary. At the central level, CAMERWA provides supplies on a cash-and-carry basis and generally does not extend credit to health facilities. CAMERWA prices are determined based on the cost of drugs or supplies plus a 10 percent markup.

Procurement and Distribution

Two national nonprofit wholesalers, CAMERWA and BUFMAR (a nonprofit mission sector foundation), procure most health commodities in Rwanda. Around 20 private sector wholesalers procure both essential and nonessential drugs as well medical supplies and laboratory reagents. Fewer drugs, medical supplies, and laboratory reagents are supplied through donations and are limited to vertical programs. CAMERWA is the main supplier for 80 percent of the essential drugs in Rwanda. Theoretically, it supplies referral hospitals and district pharmacies that in turn supply district hospitals and health centers. However, these facilities may actually obtain their supplies from CAMERWA, BUFMAR, district pharmacies, and the private sector. Orders are usually placed on a monthly basis. However, in many instances, orders are also placed on a need basis. Neither CAMERWA nor BUFMAR carries out active distribution. Even though over half of the facilities own means of transport, it is often inadequate and frequently shared with other purposes. Both CAMERWA and BUFMAR experience stock-outs of essential drugs and health commodities, which contribute to shortages at the facility level. Stock-outs in many instances are attributed to the lack of adequate quantification and the lack of data necessary for the quantification process.

Prescribing and Dispensing

About half of the health facilities have a system to record and register prescriptions; however, very few have a system to monitor drug use. Most facilities reported having a separate dispensing room, although it is not always adequate in space (57 percent) or conducive to confidentiality (37 percent). One-third of patients are not counseled on drug use.

Pharmacies lack standard operating procedures for prescribing, dispensing, and monitoring drug adverse reactions.

The Laboratory Sector

Key players in the national laboratory system include the NRL, Treatment and Research AIDS Center (TRAC), the Atelier Nationale de Maintenance, and laboratory departments at referral hospitals, district hospitals, and health centers. The NRL comprises two bodies: the National Reference HIV Laboratories and the National Public Health Laboratory. The HIV laboratory is responsible for research, drug surveillance, developing national voluntary counseling and testing (VCT) protocols, sentinels surveillance, providing referral level laboratory services, training laboratory personnel, supervision, and quality assurance and control. Some of these functions are well established but others are still in the process of being established. In coordination with TRAC, NRL tracks the availability of key VCT and PMTCT commodities.

Policies and Standards

A national laboratory policy is being developed. Policies and standards are not fully disseminated to health facilities. Two key HIV-related guidelines have laboratory elements, including some laboratory protocols, and are in use within the Rwanda laboratory system. Guidance on laboratory monitoring for ART exists within Rwanda's national ART guidelines. In early 2003, the Government of Rwanda defined minimum packages of laboratory tests to be available at different levels of the health system. The proposed minimum package does not include all ART monitoring tests specified in the national guidelines. SOPs exist but have not been tailored to individual laboratories.

Human Resources

All surveyed laboratories have at least one qualified staff person (A0 to A3 level). Staff shortage is one of top four obstacles for performing laboratory work. The average number of lab staff working at district hospitals is lower than WHO standard guidelines. Distribution of lab staff is skewed, with concentration of the largest cadre of A2 staff at referral and district labs (79 percent, collectively). This allocation of human resources supports the finding that 33 percent of health centers complain of staff shortages. Horizontal and vertical referrals have added to the workload of certain laboratories. Training in HIV-related topics has been held within the past two years, particularly on rapid HIV testing. Most labs have not received training in areas relevant to ART monitoring within the last two years, including hematology, biochemistry, and quality assurance.

Infrastructure and Equipment

Approximately one-third of the surveyed labs reported not having running water or electricity, or having inconsistent supply of at least one of the two. Insufficient supply of water and electricity hampers safety, quality of lab operations, and adequate storage conditions. A large number of labs (46 percent) do not have access to telephone within the health facility, hampering the efficiency of lab referral mechanisms and supply management systems. Centrifuges and microscopes were available and functioning in most of the labs surveyed (92 percent and 86 percent, respectively). However, other basic equipment, such as balances, autoclaves, and refrigerators, were not available in most of the laboratories. Some mechanisms are in place to

maintain nonfunctioning equipment through the District Health Authority and the Atelier National. However, maintenance mechanisms and staff capacity for fixing nonfunctioning equipment are often insufficient. In 47 percent of facilities, at least one breakdown took place during the previous six months.

Laboratory Supply Management System

A national list of essential laboratory supplies and reagents exists and has been defined by health system levels. However, these lists do not include all ART-related lab commodities required to support national laboratory monitoring guidelines for ART. Although laboratory managers are heavily involved in quantifying and ordering products for the laboratory, shortages of supplies and stock-outs are reported in almost half of the facilities, thus hampering HIV-related lab work.

Basic procedures for recording and storing information are in place; however, these are often insufficient, not standardized, or incomplete. This finding has major implications on planning ordering of supplies. Measures to guarantee confidentiality of lab records are not always in place. Lab request forms are not standardized and in many cases are used only for certain tests. Report forms are infrequently used in laboratories.

Expired reagents are found in 42 percent of facilities, implying poor stock management. Policies regarding expired products and disposal are not available. Information gathered from laboratories in the national health management information system is not being fed back to peripheral labs for performance improvement. It is not clear to what extent the Rwandan MOH uses information generated by laboratories in Rwanda for planning and resource allocation.

Quality Assurance and Quality Control

Few labs have internal and external quality control systems. These are predominantly found at referral and district facilities and are mostly geared to vertical programs. A number of labs have no standard procedures for handling specimens, recording information, and disposing of waste. Some of the labs had not adopted universal precautions for infection control (gloves) at the time of the assessment. Only 6 out of the 37 surveyed labs had policies and procedures for postexposure prophylaxis (PEP). Few labs reported having a system for internal quality controls, and in only one facility could quality control records be observed.

Referral

A referral system has been defined at the national level but appears to be implemented informally. Facilities reported that patients are being referred informally for certain tests related to ART, including CD4 tests, viral load tests, and biochemistry tests. Horizontal referral, where patients or specimens are referred between health facilities at the same level of the health system, is a common practice when tests cannot be performed by a laboratory because of lack of equipment, reagents, or expertise. Horizontal referral result in very high workloads that may even affect other services in a laboratory. Vertical referral, which occurs between levels of the health system, appears to be informal and not standardized.

Financing

Laboratory budget exists at the national level. Patients already pay for certain lab tests, although some institutions waive the required fee for indigent patients. In a number of labs, generated revenues are used to replenish laboratory supplies. Inadequacy of laboratory budget was identified as a problem at laboratories in referral hospitals.

INTRODUCTION AND BACKGROUND

Background and Purpose of the Assessment

In April 2003, RPM Plus was invited by the USAID Mission in Rwanda to examine the capacity of the pharmaceutical system to support the new USAID strategic objectives in HIV/AIDS, reproductive health, and malaria. This invitation followed an urgent request from CAMERWA (Centrale d'Achats de Médicaments Essentiels du Rwanda) to USAID for technical assistance in quantification of antiretroviral drugs being provided through the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM).

RPM Plus staff traveled to Rwanda in May 2003 to conduct a preassessment whose purpose was to diagnose commodity management problems in the health system so as to identify interventions for strengthening the pharmaceutical system in 20 districts. During this preassessment the RPM Plus team met with key informants from the health sector and representatives of important professional associations, visited relevant health facilities, and collected documents related to the health sector.[1]

In July 2003, an RPM Plus team visited Rwanda to select health facilities (49 pharmacies and 36 laboratories) for conducting a deeper assessment of the capacity to manage HIV/AIDS-related commodities for diagnosis, treatment, and care. Questionnaires adapted to the Rwandan context were distributed and completed by trained interviewers during the months of August and September 2003, and validation of data as well as data analysis took place between September and December of the same year.

The assessment's findings are intended to contribute to developing recommendations for strengthening the management of ART-related commodities in Rwanda, and consequently developing a joint action plan. For this purpose, RPM Plus has created a working group consisting of CAMERWA, DOP, the Direction de Soins de Santé (Directorate of Health Care; DSS), RPM Plus, TRAC, and WHO to discuss at length the findings obtained from the assessment with the objective of reaching consensus on recommendations. It is hoped that, after the recommendations are defined, the working group will agree on a coordinated action plan for strengthening the management of ART-related commodities at both pharmaceutical and laboratory levels. It is also expected that the benefits of these interventions would expand beyond the antiretroviral therapy program to the whole Rwandan health system.

[1] RPM Plus summaries of preliminary country assessment findings for the Prevention of Mother-to-Child Transmission Initiative, September 2003.

The Rwandan Health System[2]

Rwanda, like other African countries, initiated a process of decentralizing the health care system within three levels of medical structure: central, intermediate, and peripheral. In Rwanda, the degree of decentralization achieved has arrived only at a deconcentration of administrative activities because districts still lack the authority for allocating budgets.

Since 1995, the Ministry of Health supported by the WHO, has stated the goal of providing quality health services acceptable and accessible to the majority of the population through three main strategies: decentralizing the health system, developing comprehensive primary health care, and enhancing community participation in management and financing of services. Under this strategy, the health system is organized as follows.

Central Level

The directorates and programs of the MOH as well as some health institutions (referral hospitals) are integrated in the central level. The main functions of the central level are to elaborate and coordinate health policies and strategies and to provide technical, administrative, and logistical support to lower levels. Figure 1 represents the organization of the Ministry of Health.

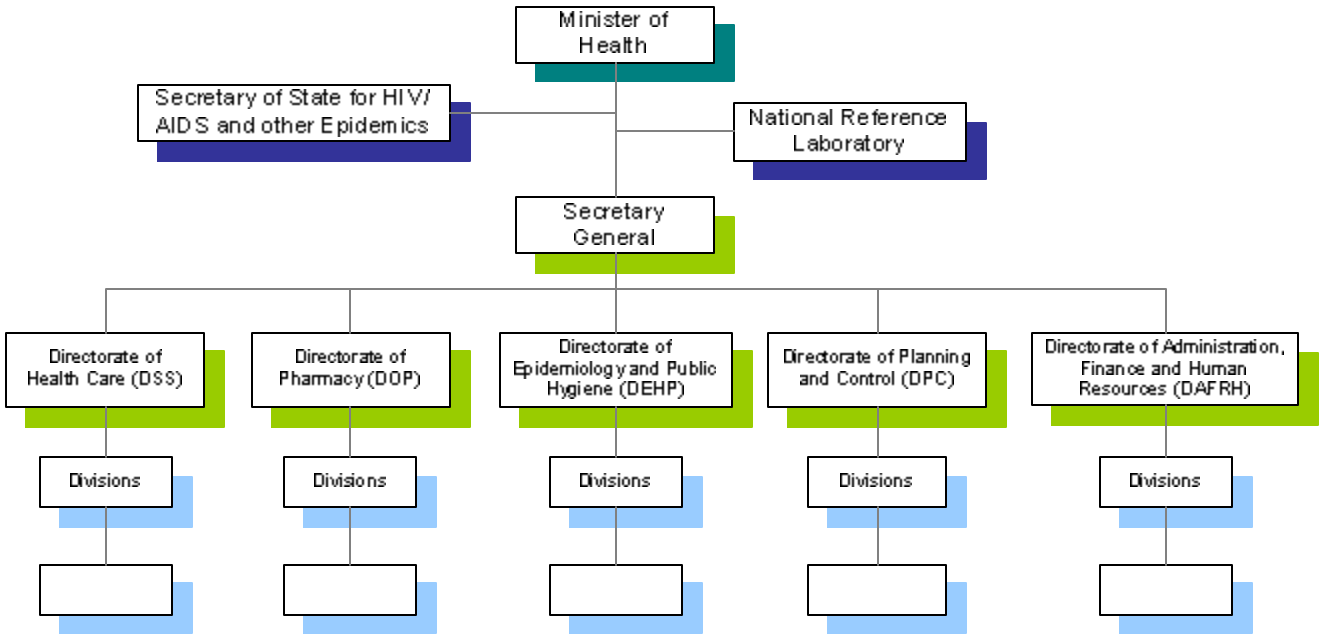

Figure 1. Organization of the Rwandan MOH

[2] The information in this section has been obtained from the "National Health Policy. Draft. January 2004," from "Plan Stratégique—Faire reculer le paludisme au Rwanda 2004–2010. Novembre 2003. Annexe 1," and from key informants in field visits conducted during 2003 and 2004.

The central level also has a function in health care delivery through national referral hospitals. There are three public referral hospitals (Butare, Kigali Hospital Centre, and Ndera) and a private national referral hospital (Roi Fayçal) integrated at this level. The University Hospital Center (CHU, from its initials in French) is formed by both Butare and Kigali Hospital Center (CHK, from its initials in French). The Ndera hospital specializes in mental health. The Roi Fayçal hospital is the highest referral hospital of the country, for both public and private sectors.

Intermediary Level

The intermediary level corresponds approximately with the area of a prefecture (province), covering various health districts, and it is located within the Provincial Directorate of Health, Gender, and Social Affairs. The main functions assigned to the Provincial Directorate are coordination of district activities and provision of logistical, administrative, and technical support to the districts, but no health care is provided at this level. The Provincial Directorate also ensures that the national policies and strategies are implemented in each region.

Peripheral Level (District Level)

The peripheral level is represented by health districts, where health care is provided. Each health district has an administrative office, one district hospital, and several health centers serving a defined population. Rwanda has a total of 39 health districts that are the basic units of the health system. The public and mission sector consists of 3 referral hospitals, 33 district hospitals, 252 health centers, and 113 health posts. The private sector contributes significantly to primary health care and consists of hospitals, clinics, *cabinets médicaux*, dispensaries, and infirmaries.

Under this structure, each health center should provide at least the Minimum Package of Activities (MPA), which includes most priority health activities, to be delivered equitably, effectively, and efficiently, according to the needs and demands of the population and to the financial constraints at the public sector. These same principles and constraints apply to the development of the Complementary Package of Activities (CPA) that would be delivered at district hospitals. CPAs include more advanced treatments, diagnostic methods, and care tha are often unavailable at health centers.

According to the UNAIDS World Report on HIV/AIDS (2000), MPAs are provided in 63 percent of the health structures. Of the 39 health districts, 34 have a functioning district hospital where approximately 90 percent of the CPAs are carried out.

Community-Managed Mutual Health Organizations: Mutuelles de Santé

The Rwandan health care delivery system is run on a pay-per-service basis. Data from a study carried out by the National Health Accounts[3] in 2000 show that the Rwandan per capita expenditure on health care was USD 12.70, 50 percent of which came from donors, 40 percent from private sources, and 10 percent from the government. Of this 10 percent, 93 percent was financed by household out-of-pocket money, 6 percent by donors, and 1 percent by the

[3] This activity was started in 1999, in collaboration with Partners for Health Reform (PHR), WHO, and USAID.

government, which represents a high burden for patients, especially in a context of high HIV/AIDS prevalence.

Since 1999, the MOH has boosted the creation of community *mutuelles de santé*, which are basic prepayment health care insurance, managed at community level, to cover at least basic packages of health care. The expansion of these *mutuelles,* which can contribute to increased equity and decrease the burden on the patients in accessing health care, in support of the Rwandan government is one of the objectives under the USAID Integrated Strategic Plan for HIV/AIDS 2004–2009.

Context of HIV/AIDS in Rwanda

Rwanda is among the 10 countries in the world most affected by HIV/AIDS. The Rwandan epidemic has common epidemiological characteristics with other East African countries, with adolescent women the most vulnerable social group. At least 5 percent of total outpatient visits in Rwanda are estimated to be related to AIDS, and the average hospital bed occupancy for AIDS patients is 25 days (twice as long as that of non-AIDS patients). AIDS patients require an average of 11 ambulatory visits per year, while the non-AIDS population needs around 3 visits annually. The number of hospital beds occupied by AIDS patients has increased from 9,000 in 1993 to 35,000 in 1997. By 1997, it was estimated that 21 percent of pediatric inpatients and 60 percent of malnutrition cases were HIV-positive.

But the HIV/AIDS context in Rwanda needs to be viewed in light of the sociopolitical crisis of the 1990s, which resulted in a sharp drop in the national economy and which contributed dramatically to the expansion of the virus, with particular negative impact on women and children. The number of households living under the poverty line has increased from 40 percent in 1985 to 60 percent in the late 1990s. Similarly, life expectancy has decreased from 50 years in 1985–1990 to 42 years in 1995–2000. Although the genocide has been a determining factor in vulnerability and poverty, the HIV/AIDS epidemic has seriously eroded the quality of life, life expectancy, and infant mortality of the Rwandan population.

The most relevant distinctive elements of the spread of HIV/AIDS in Rwanda are the massive movements of population before, during, and after the genocide of 1994 and the use of rape as a weapon of genocide. As a result, the rural areas have suffered a sharp increase in the rates of HIV/AIDS, from 1.3 percent in the mid-1980s, to 11 percent in the late 1990s. In total, about 400,000 Rwandans out of a population of 8 million inhabitants have been infected with HIV. Of those, 50 percent are women, and 13 percent are children under 15 years old. The latest available data from the National AIDS Control Commission (NACC, also called CNLS) estimate prevalence rates of 13.5 percent for the adult population (15–49 years old).

Table 1 shows the HIV/AIDS prevalence rates by age, sex, and geographic distribution.

Table 1. Distribution of HIV/AIDS by Demographic Groups

Age	Female	Male	Urban Area	Rural Area	General
12–14	4.3%	4.0%	3.0%	4.8%	4.1%
15–19	6.4%	5.9%	3.4%	8.5%	6.1%
20–24	8.6%	13.9%	15.8%	9.6%	12.3%
25–29	13.6%	21.5%	24.2%	15.5%	18.8%
30–34	10.8%	20.1%	24.2%	12.4%	17.1%
35–39	16.3%	16.4%	21.3%	13.6%	16.4%
40–44	17.4%	14.5%	20.4%	13.5%	15.6%
45–49	18.7%	10.9%	13.2%	14.1%	13.9%
> 50	14%	7.4%	6.5%	11.8%	10.3%

Source: CNLS Web page: http://www.cnls.gov.rw/cadre.doc.

The consequences of the genocide and of the HIV/AIDS epidemic have resulted in about 613,000 orphan Rwandan children 0–14 years old. By 2001, about 264,000 children had lost at least one of their parents due to AIDS, which represents 43 percent of all orphans. It is estimated that by 2015, infant mortality will increase 10 percent as a direct consequence of the HIV/AIDS epidemic.

Political Strategies in the Fight against HIV/AIDS

The Rwandan government's response against the HIV/AIDS epidemic has grown in scope and intensity from the late 1990s to the present. From 1988 to 2001, the government implemented three medium-term HIV/AIDS/STI Plans carried out by the National AIDS Control Programme (PNLS, from its initials in French). The main objectives of these plans are summarized below.

- First Plan (1988–1992): Blood transfusion safety, health education, and epidemiological surveillance were the focus.
- Second Plan (1993–1997): Preventive strategies were strengthened, and socioeconomic measures to minimize AIDS impact started to be implemented.
- Third Plan (1998–2001): Prevention, treatment, and care were included in the plan, with a special focus on participatory approaches.

In March 2001, the government of Rwanda instituted by presidential decree the National Aids Control Commission, whose main missions and objectives are—

- To assist the government of Rwanda, in its determination to put in place the implementation and coordination mechanism in the fight against HIV/AIDS
- To be an organ of coordination and planning of the activities of the institutions involved in the fight against HIV/AIDS
- To sensitize the population in AIDS control activities taking into consideration strategies and priorities of the national policy

- To mobilize resources nationally and internationally in the fight against HIV/AIDS
- To continue sensitizing and mobilizing support from the country's higher authorities in the fight against HIV/AIDS

Within the Ministry of Health, the Secretary of State for HIV/AIDS and other Infectious Diseases is the political arm in the fight against HIV/AIDS together with the Treatment and Research AIDS Center, which is responsible for biomedical aspects of prevention and care.[4] Finally, an HIV/AIDS committee is present in each province and in each district; these committees are key elements in community participation for program implementation.

ART Programs in Rwanda

In early 2003, the USAID-funded Family Health International (FHI)/IMPACT Project launched ART programs at Bilyogo Medical Center in Kigali Ville Province and in Kabgayi District Hospital in Gitarama Province. As of July 2003, FHI/IMPACT Project was managing 22 VCT sites and operating four sites with HIV/AIDS diagnosis, treatment, and care services. Three more comprehensive HIV/AIDS treatment and care sites were planned.[5] The initially selected sites are listed in Table 2.

Table 2. Initially Selected FHI/IMPACT Sites in Public and Mission Health Facilities

Site	HIV/AIDS-Related Services to Be Provided
Bilyogo (Kigali-Ville)	PMTCT + ART + VCT + Co-trimoxazole prophylaxis
Ruli (Kigali-Ngali)	Potentially for ART + Co-trimoxazole prophylaxis
Kabgayi (Gitarama)	PMTCT + ART + VCT+ Co-trimoxazole prophylaxis
Bungwe (Umutara)	VCT + PMTCT + Co-trimoxazole prophylaxis

In a second stage, additional sites were identified. These sites are listed in Table 3.

Table 3. Additionally Selected FHI/IMPACT Sites in Public and Mission Health Facilities

Site	HIV/AIDS-Related Services to Be Provided
Ruhango (Gitarama)	PMTCT + Co-trimoxazole prophylaxis
Nyarusange (Gitarama)	PMTCT + Co-trimoxazole prophylaxis
Gitarama (Gitarama)	Already has VCT and will add PMTCT + Co-trimoxazole prophylaxis

[4] The functions of TRAC are summarized in the Laboratory section.

[5] Communication from Dr. Martin Ngabonziza, Senior Technical Adviser, FHI Rwanda Country Office, July 2003.

Rwanda currently has 42 PMTCT sites and 38 VCT sites. Both types of sites are funded by various donors and TRAC. Under PEPFAR, USAID will take on 14 existing PMTCT sites and add 10 new PMTCT sites. Of these new PMTCT sites, 3 to 5 will provide ART. USAID aims to support PTMCT activities exclusive of nevirapine (NVP) provision, since that is currently being provided under the NVP donation program of Boehringer Ingleheim. As of July 2003, USAID had not yet decided where the 10 new sites would be and was thinking of expanding into geographic areas it was not yet covering.[6]

Additional related initiatives are under way. The Elizabeth Glaser Pediatric AIDS Foundation plans to support PMTCT programs. It will support nine health centers and provide five supervisors in TRAC to provide supervision for PMTCT sites. The Clinton Foundation has announced it will provide USD 200 million over five years for comprehensive care of HIV/AIDS.

The VCT Integrated Project funded by the GFATM plans to use the existing network of Rwanda's health centers to offer VCT in at least three health centers in each of Rwanda's 34 districts. This approach is part of a strategy that recognizes VCT as being the first stage in providing a larger range of HIV-related services. Therefore, the government of Rwanda plans to offer such complementary services at these same sites. VCT services to be offered will include individual, confidential counseling as well as anonymous rapid testing. Services will first be introduced in a few sites over a six-month period, with additional sites being added.

Ultimately, the national goal is to install 117 sites nationwide that provide a comprehensive HIV/AIDS diagnosis and treatment package that includes VCT, PMTCT, ART, treatment for OIs, and STI diagnosis and treatment.[7] Integrated VCT sites for the first start-up months are listed in Table 4.

Table 4. Selected Integrated VCT Sites to Start Up in Coming Months in Public and Mission Health Facilities

Province	District	Health Center	Existing Services	Services to Be Added
Kigali-Ngali	Bugesera	Nyamata	PMTCT	STI/OI/TB
Butare	Gakoma	Gikondo*	PMTCT + ART	VCT/STI/OI/TB
Cyangugu	Mibilizi	Mushaka	PMTCT	VCT/STI/OI/TB
	Gihundwe	Gihundwe	VCT + PMTCT	STI/OI/TB
Kibuye	Murunda	Murunda	VCT	PMTCT/STI/OI/TB
Gisenyi	Gisenyi	Gisenyi	PMTCT	VCT/STI/OI/TB
Byumba	Byumba	Muhura	PMTCT	VCT/STI/OI/TB
		Byumba	PMTCT + VCT	STI/OI/TB
Kibungo	Rwamagana	Rwamagana	VCT	PMTCT/STI/OI/TB

*Site not covered in RPM Plus assessment.

[6] Communication from Barbara Sow, PHN Officer, USAID/Rwanda Mission, July 2003.
[7] Communication from Solange Shengero, Coordinator, National PMTCT Program, July 2003.

Medical Assistance Program (MAP) funded by the World Bank will carry out a five-year project in 13 sites in three provinces (Butare, Cyangugu, Gitarama) targeting 2,350 patients for antiretroviral therapy. Some MAP sites overlap with Global Fund sites in terms of providing complementary activities. The government of Rwanda is trying to ensure that MAP and Global Fund sites complement each other so that Global Fund sites provide VCT/PMTCT and MAP sites provide ART, or so that each province with Global Fund VCT/PMTCT sites has one MAP ART site as a referral site for ARVs.

Table 5. Planned MAP Sites

Health Facility	Number of Patients to Be Treated
Butare Province (1 GFATM-funded health center)	
University Hospital Butare (Referral) *	300
Kabutare Hospital	150
Nyanza Hospital (existing VCT & PMTCT site)	150
Gakoma Hospital (existing VCT & PMTCT site) *	150
Gikonko Health Center *	100
Cyangugu Province (2 GFATM-funded health centers)	
Gihundwe Hospital (existing VCT site) *	300
Bushenge (existing VCT & PMTCT site) *	150
Mibilizi Hospital (existing VCT site)	150
Kibogora Hospital (existing VCT site) *	150
Gitarama Province	
Nyagatare Hospital – Umutura Province	300
Kiziguro Hospital *	150
Gahini Hospital *	150
Kibungo Hospital – Kibungo Province	150

Source: Communication from Solange Shengero, Coordinator, National PMTCT Program, July 2003.
* Not covered in the RPM Plus assessment.

METHODOLOGY

Sampling

Health facilities to be assessed were selected by a team of experts from various agencies, including CAMERWA, DOP, DSS, RPM Plus, TRAC, and WHO. A comprehensive sampling approach of the Rwandan context was developed to observe criteria related to the levels of care (referral, district, and health center) and services provided (ART, OI treatment, STI treatment, PMTCT, TB treatment, VCT) within the areas where USAID programs were in place or planned to start.

The overall sampling was conducted nationwide through the 12 Rwandan provinces (Butare, Byumba, Cyangugu, Gikongoro, Gisenyi, Gitarama, Kibungo, Kibuye, Kigali-Ngali, Kigali-Ville, Ruhengeri, and Umutura). Pharmaceutical and laboratory sites were identified so that each province has been covered in both pharmaceutical and laboratory areas. Based on these criteria, the pharmaceutical and laboratory samplings were conducted as explained in the following sections.

Sampling of Pharmaceutical Sites

The initial sample of the survey comprised a total of 62 health facilities, including three referral hospitals, 14 district pharmacies, 18 district hospitals, and 14 health centers. Annex 1 provides details on region, services delivered, and level of health care of the facilities selected. Table 6 is a summary of the sampling of public and mission pharmaceutical sites by level of health care.

Table 6. Summary of Pharmaceutical Sites Selected

Public		Mission	
Category	**Number**	**Category**	**Number**
Referral	3	Referral	0
District pharmacy	21	District pharmacy	0
District hospital	11	District hospital	9
Health center	9	Health center	8
Dispensary	1	Dispensary	0
Total	***45***		***17***

Unfortunately, some of the facilities initially selected for the sample (six district pharmacies, three district hospitals, three health centers, and one dispensary) are not included in the analysis of results because questionnaires were not adequately completed or were not answered at all. The main reasons reported for unanswered questionnaires were unavailability of staff to be interviewed, health facility found to have closed down, and health facility physically inaccessible. Hence, the sample of pharmaceutical sites referenced in this report is as shown in Table 7.

Table 7. Sample of Pharmaceutical Sites Included in the Report

Province	Referral Hospital	District Pharmacy	District Hospital	Health Center
Butare	1	2	2	
Byumba		1	1	1
Cyangugu		1	2	2
Gikongoro		1	1	
Gisenyi		2	2	
Gitarama			3	2
Kibungo		2	2	1
Kibuye		2	1	
Kigali-Ngali		1	2	4
Kigali-Ville	2			4
Ruhengeri		1	1	
Umutura		1	1	
Total	***3***	***14***	***18***	***14***

The 49 assessed pharmaceutical sites represent 12 percent of the total national sites. Referral and district facilities cover a larger proportion of the existing national facilities (52 percent on average), while health centers and dispensaries sampling is remarkably lower (5 and 0 percent, respectively), as can be seen in Table 8.

Table 8. Coverage of Assessed Public and Mission Health Facilities

Category	National Total	Sampled	Proportion
Referral hospital	4	3	75%
District pharmacy	35	14	40%
District hospital	36	18	50%
Health center	271	14	5%
Dispensary	35	0	0%
Total	381	49	12%

Finally, because not all questions in the survey applied to the 14 district pharmacies sampled, some of the quantitative analyses have been applied only to the 35 health facilities.

Sampling of Laboratory Sites

Data were collected from 36 laboratories throughout Rwanda (see Table 9). All 12 of Rwanda's provinces were covered by the survey. Five of 13 laboratories of planned MAP sites were covered in the assessment, and 8 of 9 laboratories planned for the first phase of GFATM funding were covered.

Three laboratories were surveyed in referral hospitals, 18 in district hospitals, and 15 in health centers. The laboratory assessment covered 42 percent of USAID/Rwanda-supported PMTCT sites and 4 of 5 existing and planned ART sites.

Table 9. Laboratory Survey Sample

Province	Number of Public Laboratories Surveyed	Number of Current and Planned HIV/AIDS Intervention Sites Covered by Assessment
Butare	2	MAP, 2 sites
Byumba	2	Global Fund, 2 sites 1 of 3 USAID-supported sites
Cyangugu	3	Global Fund, 2 sites
Gikongoro	1	Global Fund, 2 sites
Gisenyi	3	Global Fund, 1 site
Gitarama	5	1 of 7 USAID-supported sites
Kibungo	3	Global Fund, 1 site
Kibuye	3	Global Fund, 1 site 1 of 3 USAID-supported sites
Kigali-Ngali	5	Global Fund, 1 site 3 of 8 USAID-supported sites
Kigali-Ville	6	4 of 7 USAID-supported sites
Ruhengeri	1	None
Umutura	1	None

Data Collection Methods

The MSH/RPM Plus team developed questionnaires for assessing both pharmaceutical and laboratory sites in July 2003. Although each survey would cover major elements of pharmaceutical and laboratory management, the surveys were not intended to be exhaustive. Rather, the purpose of the questionnaires was to generate the necessary data to provide a broad but clear image of the situation of the health sector in Rwanda with respect to commodity management. This step is essential for identifying commodity management areas that require further analysis and intervention.

Questionnaires were tested in August 2003 in one urban health center by a team of two people (RPM/MSH short-term consultant and the head of the DOP), and minor modifications were subsequently made to the tools.

A team of data collectors composed of staff members from the DOP and final-year pharmacy students from the Rwanda National University in Butare was trained during a one-day workshop. The training schedule for data collectors is provided in Annex 2. Finally, the questionnaires were distributed among the data collectors according to the sampling planned and were appropriately filled out.

Data Analysis Methods

Data analysis was carried out using indicators linked to key questions in the survey. Pharmaceutical sector indicators were selected based on indicators already tested by WHO, RPM

Plus, and other organizations.[8] Laboratory indicators were selected based on key elements of readiness identified through RPM Plus's experience with laboratory commodity management for ART programs in Mombasa, Kenya.

Pharmacy and laboratory data were entered into separate Excel spreadsheets, and both qualitative and quantitative analyses were carried out. The analysis was done according to seven main variables identified—

- Existence of policy and standards
- State of infrastructure
- Human resource training and levels
- Availability and access to key health commodities
- State of financing for health commodities
- Functionality of management information systems
- Enabling environment

Key pharmaceutical and laboratory-based indicators were used to represent these variables of the survey and results were presented in tables and matrices.

[8] Reference key indicators.

PHARMACEUTICAL SECTOR

Organization of the Pharmaceutical Sector

A number of institutions comprise the pharmaceutical sector. The Direction de la Pharmacie within the Ministry of Health is responsible for both the public and private pharmaceutical sector in Rwanda. The DOP's main responsibilities include developing and implementing national drug policy, developing and coordinating drug registration systems, certifying and regulating establishments that sell drugs, and providing drug information to providers and consumers.

CAMERWA is the main supplier of drugs and medical commodities to the health sector in Rwanda. It was created in 1998 by the Rwandan government with the mandate of ensuring the population's physical and financial access to quality pharmaceuticals. CAMERWA is a private entity with autonomous management; its social purpose is serving the public sector. CAMERWA provides generic essential medicines, medical supplies, and laboratory reagents and consumables. CAMERWA is the only supplier with authorization to import ARV drugs.

Stand-alone district pharmacies are located in each health district to supply public health facilities with health commodities that are procured from CAMERWA. Then, pharmacies are located within public health facilities at all levels of the health system (district hospitals and health centers) to provide drugs and medical supplies to outpatients and to supply inpatient services. Figure 2 shows the major actors in both the public and private pharmaceutical sector in Rwanda.[9]

[9] Key informant interviews.

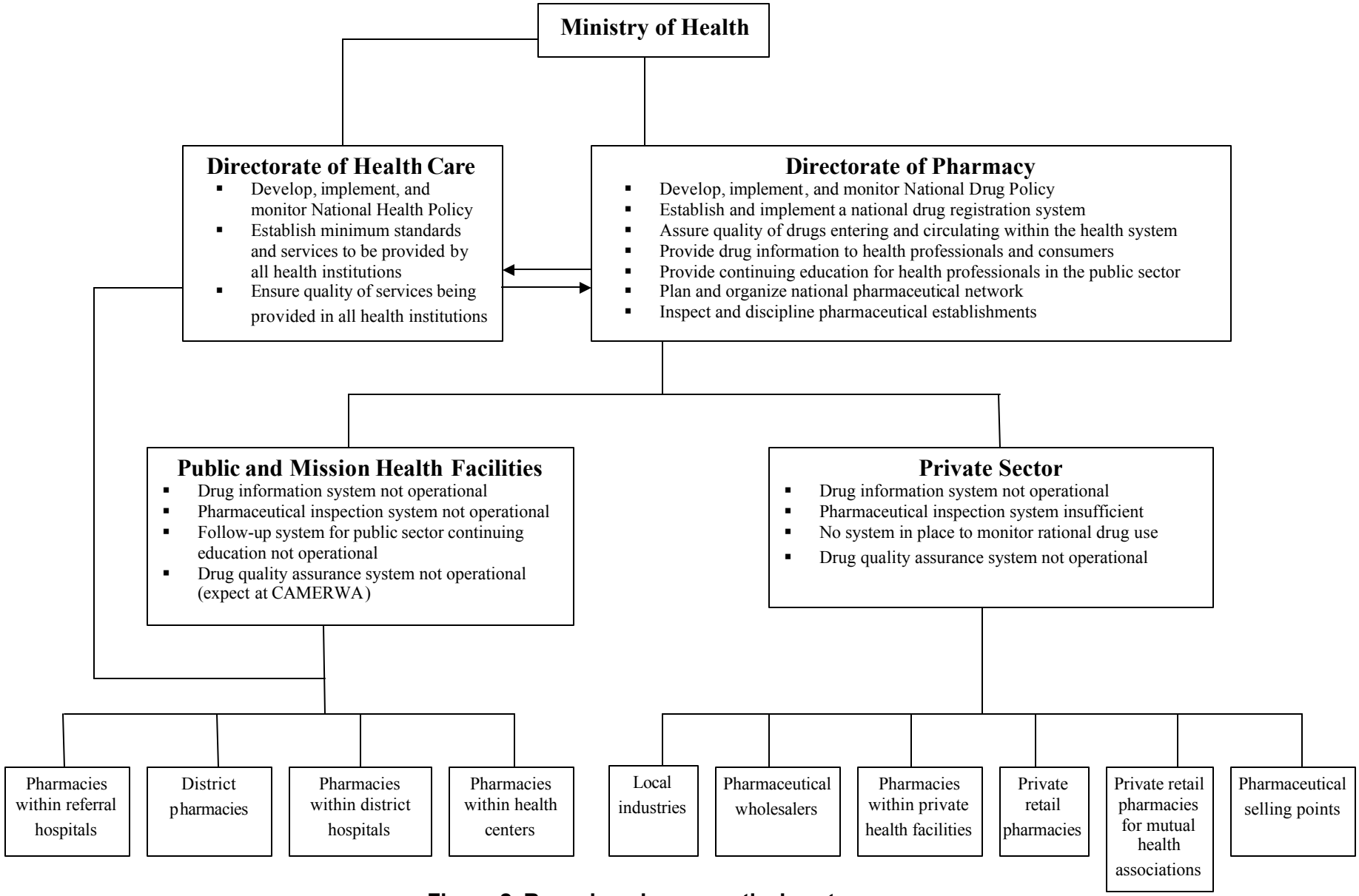

Figure 2. Rwandan pharmaceutical sector

Personnel Working in the Pharmaceutical Sector

Persons working in the pharmaceutical sector in Rwanda consist of pharmacists and other health personnel such as nurses. Other cadres within pharmacy, such as pharmacy technologists and pharmacy assistants, do not yet exist in Rwanda. Rwanda has about 100 pharmacists nationwide, the majority of whom work in the private sector, mainly located within the city of Kigali.

Pharmaceutical Sector Supply

The main supplier to the pharmaceutical sector in Rwanda is CAMERWA, which provides 80 percent of essential drugs in Rwanda. CAMERWA also distributes medical supplies and consumables, as well as some laboratory test kits and reagents. CAMERWA charges the cost of supplies plus 20 percent. It provides supplies on a cash-and-carry basis and generally does not extend credit to health facilities.

In principle, CAMERWA is supposed to directly supply public and private referral hospitals and district pharmacies. District pharmacies in turn supply district hospitals and health centers in their corresponding districts. Health centers and district hospitals are therefore supposed to place orders to district pharmacies, which forward the orders to CAMERWA. District pharmacies and referral hospitals are responsible for picking up supplies from CAMERWA, because CAMERWA does not currently deliver supplies to its client facilities.

In reality, however, this system is not followed. Referral hospitals procure some of the drugs through CAMERWA but they also import drugs directly (mainly specialties). Then, district pharmacies buy drugs from CAMERWA or from the private sector, and district hospitals and health centers might obtain their drugs either from district pharmacies or from other sources, including direct supply from CAMERWA. Therefore, access to CAMERWA and to the private sector is unrestricted at all levels of health care, and the function of district pharmacies remains unclear.

Additional suppliers to the pharmaceutical sector are BUFMAR and private wholesalers. BUFMAR represents various church denominations and supplies more than 100 client institutions, including mission (church) and public health sectors. BUFMAR provides primarily essential drugs but does not stock certain items, such as HIV test kits, and does not buy antiretroviral drugs. Like CAMERWA, BUFMAR is not involved in distribution of supplies. Client institutions therefore must pick up supplies in person. In general, BUFMAR has higher prices than CAMERWA, due to air freight costs. BUFMAR carries out continuing education for its client institutions through training weekends held four times per year and focused on various health topics selected by client institutions. BUFMAR was involved in organizing the first MSH- and WHO-sponsored Promoting Rational Drug Use course presented in French in July 2003.

Figure 3 shows the flow of supplies through Rwanda's pharmaceutical sector.

About 20 private sector wholesalers procure both essential and nonessential drugs as well as medical supplies and laboratory reagents. However, private sector pharmacies were not included in the survey. Fewer drugs, medical supplies, and laboratory reagents are supplied through donations. These tend to be limited to vertical programs such as tuberculosis (drugs) and HIV/AIDS (drugs and test kits).

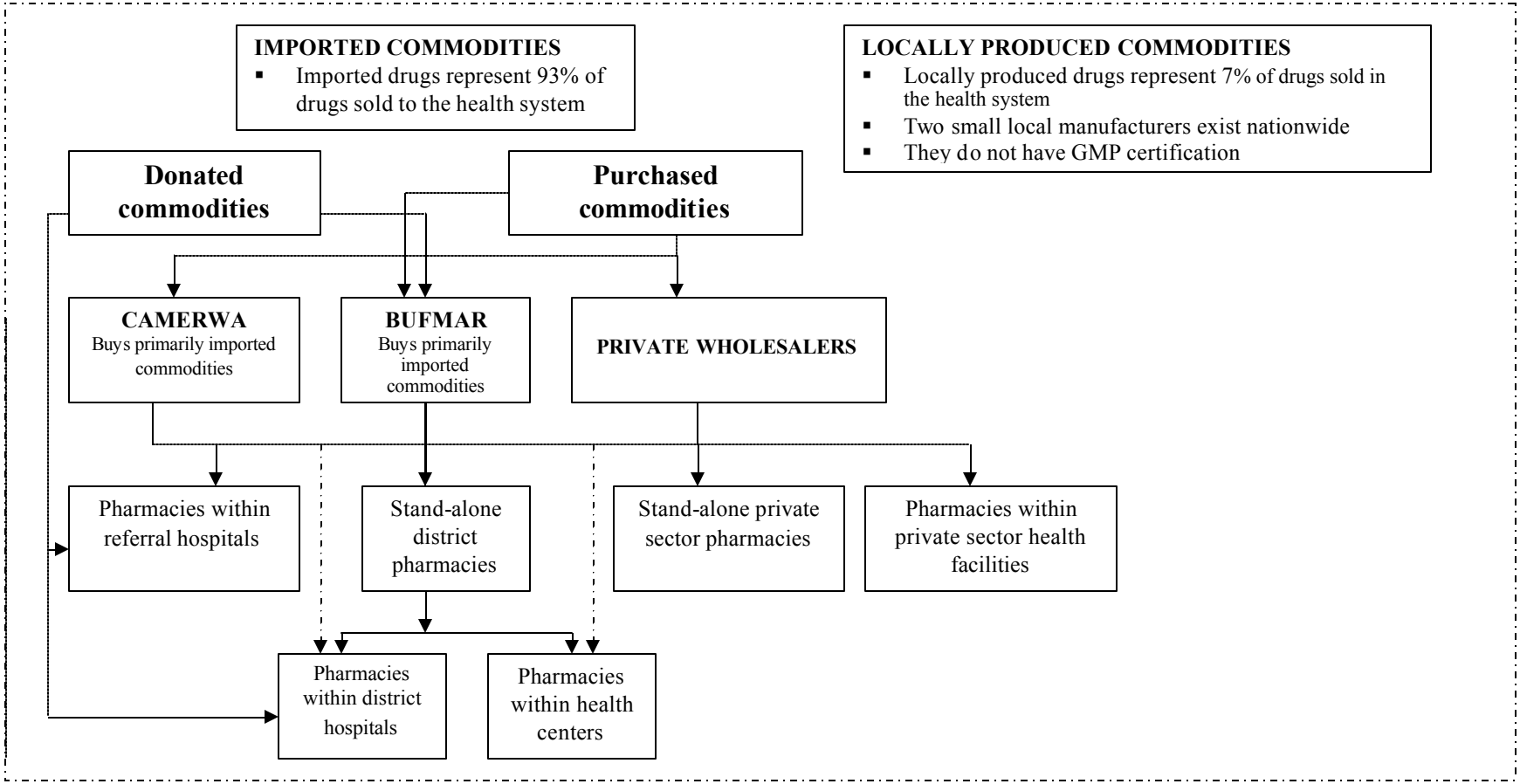

Figure 3. Flow of commodities through the Rwanda public health system

Patient Drug Supply within the Pharmaceutical System

The most basic level at which patients can obtain drugs in the public sector is the dispensaries (or small pharmacies) placed in health centers. After a paid consultation in the health center, the patient receives a prescription that is an indispensable prerequisite to obtain the drugs at the dispensary. These dispensaries are usually run by nurses.

More-sophisticated drugs are available from pharmacies within public district and referral hospitals. Given the paucity of pharmacists in Rwanda's public health system, most pharmacies within these health facilities are managed by nurses.

Patients also obtain drugs from private pharmacies. Located throughout Rwanda, these private pharmacies are often small shops or marketplace stands. Medical and pharmaceutical expertise available at these private pharmacies varies—some have trained clinical personnel and others are run by individuals with no expertise or training. Prescriptions are not required at these sites to dispense drugs, and a number of patients obtain drugs without first visiting a health facility.

Pharmaceutical Sector Survey

Policies and Legal Framework

A national drug policy is a document created by a government to provide a framework for coordinating activities of all actors in the public and private pharmaceutical sector. Such a policy contains goals set by the government for the pharmaceutical sector and the main strategies for attaining them. Some important aspects to be regulated are those related to staff, registration of drugs, price setting, and quality assurance and quality control mechanisms.

Findings

Two important laws related to the pharmaceutical system exist in Rwanda. The first, called "L'Art de Guérir," was gazetted in 1998 to establish a legal framework for medical, dental, and pharmaceutical care.[10] Then, in 1999 "L'Art Pharmaceutique"[11] was approved, providing a general framework for various aspects related to the pharmaceutical sector. However, implementation of these laws has been hampered by the lack of the ministerial instructions that are necessary to provide the detailed procedures for applying regulations to each context. As an example, although L'Art Pharmaceutique contemplates the creation of the National Committee for Drug Registration, this committee has never been created, leaving Rwanda without a national system to register drugs and, therefore, without a legal framework to provide basic quality assurance. Another deficit of the Rwandan legal framework concerning the pharmaceutical sector is the absence of a National Drug Policy (NDP), although the process of creating one has started. A draft document is being finalized among the DOP in collaboration with other key Rwandan professionals and it is expected to be finalized and approved during 2004.

[10] N° 10/98 of 28/10/1998.
[11] N° 12/99 of 02/17/1999.

Another important element in the standardization of pharmaceutical procedures is the development and establishment of a National Essential Drug List and standard treatment guidelines to guide clinicians and pharmacists in providing correct care to patients. Rwanda has had an EDL list since 1997, in which drugs, medical supplies, and laboratory commodities are organized by level of care. STGs exist for a number of illnesses, including HIV/AIDS, tuberculosis, and malaria. However, the availability of these documents (STG and EDL) is not ensured in all health facilities. All referral hospitals and more than 80 percent of district hospitals and health centers (82 and 85 percent, respectively) were found to have the EDL in the facilities, but the document was found in only 64 percent of the district pharmacies.

With regard to the STGs, the survey focused on the various guidelines on HIV/AIDS already developed in Rwanda in a number of areas of care, including ART, OI, STI, and VCT. One of these is the Antiretroviral Therapy Guidelines first published in 2001 and due to be updated in 2004. TRAC officially introduced the guidelines in all 34 district hospitals in 2003 through a comprehensive training plan for nurses and physicians.[12] Overall, about one-third of facilities were aware that these documents existed, with awareness being highest at referral facilities and lowest at district pharmacies. But as can be observed in Table 10, the availability of the documents varied among the different facilities.

Table 10. Availability of HIV/AIDS-Related Documents in Public and Mission Health Facilities

Document N = 49	All Facilities Surveyed	Level of Care			
		Referral Hospital	District Pharmacy	District Hospital	Health Center
Awareness of existence of documents	27%	67%	21%	29%	23%
Guidelines ART adult and child	10%	67%	0%	6%	15%
Guidelines ART and monitoring	18%	100%	0%	12%	31%
Guidelines for prescription of ARV drugs	16%	67%	0%	24%	15%
Guidelines for clinical management of HIV/AIDS patients	11%	100%	0%	6%	15%
Guidelines for medical management HIV/AIDS including OI	24%	67%	7%	24%	38%
SOP for OI	27%	67%	7%	29%	38%
Guidelines STI	57%	67%	29%	65%	85%
Correct manual for corresponding level of care	8%	33%	7%	0%	15%
Guidelines VCT	39%	67%	7%	59%	46%
Guidelines for home-based care of HIV/AIDS	4%	33%	0%	0%	8%

[12] The training was given after this survey. Figures in this report are based on survey and do not include this training. A second training is planned for February 2004.

Most of the facilities (90 percent) reported having VCT guidelines, but, overall, only 10 percent of health facilities reported having ART guidelines and only 11 percent have guidelines for clinical management of HIV/AIDS. Although the referral hospitals are the main dispensers of ARVs, not all relevant guidelines are available at that level. The least-available guidelines were the home-based care guidelines, and the most-available guidelines were the STI guidelines. (The questionnaire did not ask about PMTCT guidelines.)

When analyzed by level of care, HIV/AIDS-related guidelines appear to be more available at referral hospitals and less available at district hospitals and health centers. Guidelines are markedly absent at district pharmacies. For example, no district pharmacies were found to have ART and monitoring guidelines, whereas all referral hospitals, 12 percent of district hospitals, and 31 percent of health centers had these guidelines available.

Discussion

Although the foundations of the pharmaceutical legal framework have been established with the existing laws, their deficient implementation is hampering the quality of the health care in Rwanda. A major aspect is the lack of registration procedures, which not only hampers the possibility of establishing mechanisms to assure drug quality, but also constrains quantification because it is not clear what volumes and types of drugs are circulating in both public and private sectors.

With regard to STGs, despite the efforts already made to develop a variety of guidelines to combat and mitigate the effects of the HIV/AIDS epidemic through the health care system, efforts need to be made to improve awareness, demand and distribution of STG within the whole public sector. The distribution of key guidelines, such as clinical management, OIs, ART management, and VCT, needs to reach all health facilities, with special emphasis in district pharmacies where guidelines have been found to be notably unavailable. In order to increase awareness of and demand for STGs and to guarantee their correct use, the distribution of guidelines should be accompanied by training programs. All staff involved in HIV/AIDS patient management should be targeted in training programs, including pharmacists and pharmacy staff, who up to now have not been actively involved.

Human Resources: Staffing Levels

Findings

Availability of appropriately qualified and motivated staff in pharmacies is important for pharmaceutical management in general, and for HIV/AIDS treatment programs in particular. Sufficient numbers of staff allow for division of labor within the pharmacy, which in turn increases efficiency and quality of services. ART in particular requires adequate time for drugs counseling. Additionally, division of functions in the pharmacy reduces opportunities for committing fraud.

Table 11 summarizes the percentage of pharmacies at each health level and the different cadres of staff they have.

Table 11. Distribution of Staff

Level of Staff N = 49	All Facilities Surveyed	Level of Care			
		Referral Hospital	District Pharmacy	District Hospital	Health Center
Pharmacist	2%	100%	0%	0%	0%
Nurse A2	86%	100%	100%	76%	92%
Nurse A3	6%	0%	7%	0%	15%
Other	27%	33%	29%	41%	8%

According to the survey, in most health facilities, pharmacy activities are performed by nurses-A2. Pharmacist is the only cadre that receives formal pharmacy training, since no pharmacy technicians or assistants exist in the country. All pharmacists were found to be concentrated at referral hospitals.

More than a quarter of the health facilities employ persons with a training level designated "other." Information obtained during the interviews revealed that health facilities often hire staff with primary or secondary education, who receive only basic on-the-job training. Therefore, it could be assumed that the category "other" is likely to include support staff without formal pharmaceutical or medical training.

The lack of staff specifically trained for pharmacy seems to have an impact in the continuity of the staff working in the pharmacy. Field data collection gave an overall impression that a large number of people trained in pharmaceutical management were actually not working in pharmacies. In the instances where this phenomenon was noted in the field, it was not clear why people left their posts and whether these employees were working within the same health facility. An additional visit by the RPM Plus team (December 2003) to one of the rural health districts confirmed the impression that people are moving away from the pharmacy because they prefer to work at the level of their formal training (mainly nursing).

Discussion

Although interviewers observed that the number of staff assigned to the pharmacies generally did not seem to be a problem, some facilities expressed concerns about the increased workload anticipated with the introduction of ART. Further investigation is needed to ascertain whether the number and distribution of pharmacy staff is adequate for the current and new pharmaceutical activities. The expansion of ART will involve introduction of new drugs and necessary control systems to ensure adequate supply management and drug use.

Problems related to turnover and lack of motivation of pharmacy staff that were perceived during the survey should be studied further at health facilities. A possible area of action could be to complement supply management training with training in other areas closer to nurses' interests, such as rational use of drugs, and that are essential to the success of ART implementation. Other possible areas of work include enhancing pharmacy responsibilities and establishing mechanisms to integrate pharmacy staff with other clinical staff.

Human Resources: Training

Findings

Training of pharmacy personnel in key areas of drug management such as inventory management, dispensing, and drug counseling provides pharmacy staff with the tools to increase efficiency and quality of services. Making up-to-date reference materials available is an important contribution for continuing education and for keeping pharmacy staff abreast of new information related to drug use and pharmacy management.

Training is of key importance in HIV/AIDS treatment programs because the drugs involved are complex and new to most health providers in health systems. Many pharmacists, physicians, and nurses have not been exposed to HIV/AIDS-specific training during preservice training. In-service training and continuing education are therefore critical to introduce and update health professionals' knowledge in HIV/AIDS-related issues. An additional challenge of ART is that because information and research advance rapidly, recommendations on drug use change, and health professionals need to respond effectively to therapeutic research progress.

Health facilities were asked whether training had been provided for pharmacy staff in a number of key areas, including procurement, store management, rational drug use, and antiretroviral therapy.

Less than half of pharmacy staff reported having been trained in drug procurement. Similarly, less then half of pharmacy staff had been trained in rational drug use. Approximately one-third of pharmacy staff had been trained in store management; lack of such training can contribute to inappropriate quantification and store management.

With respect to training specifically related to HIV/AIDS, less than half of pharmacy staff had been trained in VCT. Few pharmacy staff had been trained in ART management, including prescribing, monitoring, rational use, and adherence. Approximately one-third of pharmacy staff had training in HIV/AIDS prevention. Virtually no pharmacy staff at all health facilities had been trained in HIV/AIDS-related supplies management.

Table 12 summarizes the reports of facilities regarding training received by their staff, either in pharmaceutical management or in management of HIV/AIDS.

Table 12. Pharmacy Staff Training

Training Received N = 49	All Facilities Surveyed	Level of Care			
		Referral Hospital	District Pharmacy	District Hospital	Health Center
Drug procurement	41%	33%	64%	35%	31%
Store management	37%	33%	43%	41%	31%
Rational drug use	45%	33%	64%	47%	31%
Managing drug supplies for HIV/AIDS	4%	33%	0%	6%	0%
Prepared for ART	20%	100%	0%	18%	31%
Prepared for VCT	41%	100%	7%	53%	54%
Prevention of HIV/AIDS and OI	37%	67%	29%	35%	46%
Treatment of HIV/AIDS and OI	24%	67%	21%	29%	15%
ART drugs monitoring treatment/ rational use/adherence	18%	67%	0%	29%	15%
TB therapy	39%	67%	7%	41%	69%
Other (unknown)	4%	0%	7%	41%	31%

The perception overall of the pharmacy staff is that they need further training in a number of areas related to drug management in general, as well as in HIV/AIDS. Table 13 summarizes responses from facilities with respect to perceived training needs. Most respondents reported that they required more training in key aspects of commodity management—specifically in drug procurement, rational drug use, and store management, which is consistent with the lack of training reported in health facilities. Approximately 22 percent of pharmacy staff expressed the need for "other training." Qualitative information from questionnaires revealed that these other areas include computerized systems for commodity management and reliable methods of quantification.

When asked about training needs specific to HIV/AIDS treatment, most respondents indicated that they needed more training in various aspects of HIV/AIDS treatment, care, and support. Almost all of the actual pharmacy staff requires training at all levels of HIV/AIDS-related matters. A high majority of facilities reported requiring training in all areas of prevention and treatment of HIV/AIDS.

Table 13. Pharmacy Staff Perceived Training Needs

Training Needs N = 49	National Total	Level of Care			
		Referral Hospital	District Pharmacy	District Hospital	Health Center
Drug procurement	86%	67%	100%	82%	92%
Rational drug use	82%	100%	93%	76%	85%
Stores management	84%	67%	93%	82%	92%
Other areas of training (not related to HIV/AIDS)	22%	33%	29%	24%	15%
Prevention and treatment of HIV/AIDS	76%	100%	79%	65%	92%
Prevention and treatment of OI	73%	100%	71%	65%	92%
Utilization and monitoring of ARV drugs	88%	100%	93%	82%	100%
Management of ARV drugs and supplies for HIV/AIDS	86%	100%	86%	82%	100%
TB therapy	69%	100%	64%	59%	92%
Management information system of ART	88%	100%	93%	82%	100%
Other areas of training (related to HIV/AIDS)	2%	0%	0%	1%	0%

As seen in Table 14, 31 percent of the health facilities reported feeling ready to introduce ART within the following month, and about 24 percent reported not being ready.

Table 14. Perceived Readiness of Public and Mission Health Facilities to Introduce ART

Level N = 49	National Total	Level of Care			
		Referral Hospital	District Pharmacy	District Hospital	Health Center
Already in place	8%	67%	0%	6%	8%
Health facility ready to introduce ART within the following month	31%	67%	21%	29%	38%
Health facility not ready to introduce ART within the following month	24%	0%	36%	12%	38%
Do not know	29%	0%	36%	41%	15%

Facilities were also asked about their access to reference materials and continuing education opportunities. Although approximately half of facilities reported having textbooks, only one-third of facilities had access to medical journals and publications. Referral hospitals had the highest access to medical journals and publications (67 percent) while health centers were found to have the lowest access (15 percent). Direct observation by data collectors found that, in many cases, reference materials were outdated. Health centers reported the highest access to continuing education courses (46 percent), while referral hospitals reported having no access at all. The overall access to continuing education courses was 35 percent.

Discussion

Despite the fact that one-third of the health facilities reported being ready to introduce ART promptly, the vast majority of the health facilities have expressed needs for training in all areas of drug management as well as in HIV/AIDS patient management, including ART. The discrepancy between perception of readiness and need of training could be understood from a context in which scaling up ART is urgent. Adequate training will raise consciousness among the health staff of the necessary steps for introducing ART with effectiveness, quality, and safety.

Establishing affordable mechanisms for providing updated information to pharmacy staff at all levels of the health system has been identified as a challenge and a need. A harmonized system should be developed throughout the health sector to update staff through continuing education courses, technical updates, presentations, and the like. Pharmacy reference materials are required at all levels of the health system.

Since all interventions are constrained by limitations of resources and time, training areas should be prioritized and targeted according to needs, opportunities, and rational use of personnel skills. For example, should pharmacy staff receive training in VCT or should this particular training be targeted only to counselors, while providing pharmacy staff with training in other areas related to drug counseling?

Pharmacy Supply Management: Infrastructure and Equipment

Availability of sufficient and appropriate physical infrastructure, furniture, and equipment is a key element for facilitating proper storage of drugs and medical supplies. It also contributes toward maintaining the quality of pharmaceutical supplies and dispensing activities.

The survey asked about various dimensions of infrastructure, including availability of sufficient space to allow for separation of functions such as storage and dispensing of drugs. Data collectors were also asked to make observations on the storage conditions. Availability of equipment focused on the existence and adequacy of furniture including cupboards and office equipment, and other items such as shelving, refrigerators, and pallets.

Findings

When asked about dimensions of storage space, 56 percent of health facilities reported having storage spaces smaller than the standard requirement laid out at the national level for health, and half of them expressed the need for additional storage space. Of facilities surveyed, 61 percent reported having separate storage areas for drugs and medical supplies. Dangerous and inflammable products were adequately stored in separate spaces in 43 percent of the facilities. About three-quarters of the sites (76 percent) were found to have independent storage and dispensing rooms.

Maintenance of building infrastructure was found to be adequate in most of the stores. Data collectors found that 98 percent of facilities were clean; 95 percent had walls in good condition. From those sites that reported problems, leakages in walls and roofs seemed to be the main

concerns. However, less than half of facilities (47 percent) reported having a reliable supply of electricity, and 35 percent of facilities reported experiencing power cuts on a daily basis. Refrigerators were available in 78 percent of the facilities, but functional in 73 percent of the sites.

With respect to the adequacy of the equipment available, 43 percent of facilities indicated that equipment in the pharmacy needed improvement. Most facilities (98 percent) reported having shelving, 45 percent of facilities reported using pallets for storage, and 64 percent reported having cupboards. Office equipment was available in 82 percent of the sites.

Direct observation of some facilities found that many of these storage spaces were not constructed for the storage of drugs and medical supplies, which could explain their inadequacy in some cases. The survey found that ventilation was not always ensured (70 percent for main storage, 43 percent for other rooms). Protection from light was adequate in most of the main storage areas (98 percent) but insufficient in other rooms (53 percent), some of which are planned to house ARVs. These observations are important for drug storage in general and even more for some ARVs, which are heat or humidity labile and therefore require adequate ventilation. Overall, only 53 percent of the facilities had an area adequate for ARV storage.

Another important aspect that especially affects ARVs because of their high value is security. In 86 percent of the facilities, doors and windows were found to be reliably locked, but 16 percent of health facilities reported having experienced break-ins within the past two years. It is generally recommended to store ARVs in lockable cabinets and to introduce a special registration processes to prevent leakage. Availability and adequacy of lockable cupboards were assessed in the survey, which found that only 33 percent of the facilities had adequate cupboards in terms of security, and only in 22 percent of the cases was the space of the cupboards adequate.

Discussion

Two main aspects are important to consider when analyzing the data on storage infrastructure. First, in many facilities the current space that houses drugs and medical supplies was not built with that purpose. Second, although the Ministry of Health developed standard pharmacy guidelines for space, most health facilities were constructed before these guidelines came into existence.

Overall, around half of the health facilities require better storage places to reach the minimum requirements necessary for drug storage in general that are also essential for introducing ARVs. These requirements include making repairs to infrastructure (mainly wall and roof leaks), providing adequate equipment (including shelves, lockable cabinets and lockable refrigerators), and improving ventilation and protection from light. Because these aspects might vary broadly from facility to facility, more in-depth work is required to identify means of fulfilling these requirements under MOH guidelines.

Security mechanisms should be introduced to control the entry of unauthorized personnel in the pharmacy areas as well as to prevent break-ins. Maintenance of doors and windows should be conducted, and lockable cupboards will be needed for storage of ARVs. The establishment of

security measures applies not only to stores but also to all pharmacy areas for controlling drugs in general and ARVs in particular, and for protecting confidential records.

When lockable cabinets are to be purchased for ARVs, it might be necessary to do a trial quantification of ARVs in accordance with the capacity of the facility and possible projections for the future, since the space required to store those drugs may be higher that expected.

Pharmacy Supply Management: Store Management

Store management includes a broad range of operations for internal flow of drugs and medical supplies, and related paperwork activities, as well as the physical organization of the store (location and classification of supplies, handling procedures, and so on). However, this survey did not include in-depth questions concerning all these areas. Here are presented some findings regarding inventory control, storage of controlled drugs and ARVs, and waste management.

Inventory Control

Accurate inventory control is essential to facilitate quantification, to avoid stock-outs, to prevent drugs from expiring on shelves, and to control possible theft and misuse. Ideally, health facilities should develop an internal system for checking stock levels at various dispensing points. Such a mechanism assists in detecting fraud and in pinpointing where health commodities may be leaking from the health system. Additionally, such a mechanism gives a more accurate assessment of the availability of stock within a health facility. For example, a certain drug might be out of stock in the main store of a facility while at the inpatent wards or the outpatient dispensing points it might be sufficiently supplied.

Although 86 percent of the facilities reported having regular inventory controls, a field visit conducted in December 2003 revealed some frequent basic errors in bin cards and in stock keeping. Record-keeping practices on stocks using bin cards was being poorly done. There were a number of mistakes in filling out bin cards, and stock balances were frequently not recorded. Record keeping was so incomplete at times that it was impossible to tally monthly consumption information from which to calculate average monthly consumption.

These observations are consistent with the fact that only in 37 percent of the facilities had staff received training in store management, as shown in Table 10. However, training alone seems not to be enough without adequate supervision, because some of these facilities reported that staff had indeed had access to training in stock management and record keeping for pharmaceutical supplies within the past two years. The fact that one supervisor admitted not being sure what to look for in ensuring proper recording is indicative that training activities should be appropriately integrated and coordinated at different levels.

Storage of Controlled Drugs and ARVs

In the previous section on Infrastructure and Equipment it was mentioned that a number of changes should be introduced in pharmacy stores to ensure storage quality, and that security

mechanisms should be put in place. However, all these interventions should be accompanied with adequate training in store management to achieve effective results.

The introduction of ARVs requires the establishment of and compliance with special measures of security, including the use of lockable locations (cupboards and refrigerators) as well as especial recording mechanisms, such as those used for narcotics. However, observations from field visits revealed that controlled drugs are not always adequately kept. Observations from field visits revealed that in certain facilities narcotics were stored with ordinary drugs, and the door to the pharmacy where these drugs were stored was unlocked and accessible to the public.

Waste Management

Expired drugs and other pharmaceutical wastes need to be adequately eliminated to avoid environmental contamination and health risks. Only 59 percent of the facilities reported having a functioning incinerator: 100 percent at referral hospitals, 43 percent at district pharmacies, 65 percent at district hospitals, and 69 percent at health centers. Further investigation is needed to identify the usual procedures for eliminating pharmaceutical wastes at those facilities where an incinerator is not available.

Pharmacy Supply Management: Availability of Products

Availability of health commodities at each facility is an important indicator of performance. Shortages or stock-outs of key drugs and medical supplies discourage patients from visiting health facilities and can even deter them from using the health system at all.

To assess the availability of drugs, a list of tracer drugs was developed. Health facilities were asked to fill in the number of days each tracer drug was out of stock between July 2002 and June 2003. Annex 3 shows the tool used at the facilities with the list of tracer drugs.

Findings

Only 25 percent of health facilities filled in this form, and 75 percent of health facilities did not provide any information about the number of tracer drugs that had been out of stock during that period of time. Although referral hospitals did not report problems with availability of essential drugs, 37 percent of the facilities reported having experienced stock-outs of essential drugs, including 50 percent of the district pharmacies, 35 percent of district hospitals, and 38 percent of health centers. No clear patterns emerged with respect to drugs that were found to be out of stock across health facilities.

In general, no data were available about stock levels for ARVs, which was not surprising, because very few health facilities currently administer ARVs. The only facility that reported stock-outs of ARVs had just started the ARV program.

In order to obtain more information about the lack of data provided and details of the stock-outs reported, a follow-up visit was conducted during December 2003 to three facilities (health center, district pharmacy, and district hospital) within the same district. These visits revealed that

the lack of data about stock-outs was related to inadequate inventory control, previously explained.

Discussion

Most health facilities surveyed (75 percent) did not provide information on stock-outs, perhaps owing to poor record-keeping practices as observed during the field visits.

Although stock-outs in CAMERWA and BUFMAR were not assessed, complaints about stock-outs at both suppliers were often reported during the data collection at facility sites. Further investigation is needed in order to determine the causes and possible solutions regarding availability of drugs and other commodities at all levels of health care, and performance indicators are recommended to be established.

Pharmacy Supply Management: Quantification

Quantification is a key function in health commodity management that refers to the process of estimating needs for quantities of specific health commodities during a specific period of time. Accurate quantification requires various pieces of information. These include the EDL, average consumption, epidemiological (morbidity) information, prescription patterns, minimum and maximum stock levels, frequency of stock-outs, and length of the procurement cycle. All these elements make quantification a complicated exercise, which is highly vulnerable to mistakes. Even when quantification is done accurately, the ability of a health system to ensure a full supply pipeline can be limited by the cash available to health facilities for purchasing required items.

Findings

The questionnaire covered a number of aspects related to quantification. Facilities were asked what types of data were used to quantify health commodity needs. It was found that quantification is usually done by the person in charge of the pharmacy. Historical consumption data were reported to be used by 95 percent of the facilities, while 14 percent use epidemiological (morbidity) data. Most facilities (95 percent) use data on minimum and maximum stock levels in quantification. Stock-out data is used by only 41 percent of the health facilities in quantifying health commodities. Eleven percent of facilities reported cross-checking quantification findings using different quantification methods.

Almost half (48 percent) of health facilities indicated that quantities of health commodities were determined using availability of cash/budget. The procurement cycle was taken into account by 80 percent of the facilities, while back ordering is seldom used in the procurement cycle (16 percent).

The frequent stock-outs in CAMERWA reported by the facility sites might be a sign of problems in quantification, which is also consistent with their perceived need of technical support for quantifying ARVs.

Discussion

The inadequate inventory control management detected at facility level in the survey is itself an important obstacle to implementation of accurate quantification mechanisms, at both facility and central levels. In order to establish a quantification system at national level, information has to be gathered at facility level, and mechanisms have to be established to allow the information to flow from the districts to central levels, where processing and analysis of data should be performed. Therefore, the lack of a management information system (MIS) for gathering, processing, and analyzing data is a determinant factor in establishing a quantification system. Adequate training in quantification for different levels of health care will also be required. However, even when quantification is accurate, fluctuation of prices, budget constraints, and lack of cash might hamper the availability of drugs.

Pharmacy Supply Management: Selection of Drugs

As described earlier, Rwanda has had an EDL since 1997. The latest version was updated in 2002 and includes essential drugs, laboratory reagents, and medical supplies.

Selecting a limited number of essential drugs to be used at each facility has a number of advantages. It simplifies the supply chain management, which can be remarkably beneficial in locations with shortage of trained staff. In such cases, a limited number of drugs can result in lower costs to the facility and eventually to the health system. Finally, it facilitates the promotion of rational drug use.

Findings

Data from the survey revealed that a significant number of health facilities purchase drugs, medical supplies, and laboratory reagents not available in the Rwandan EDL. Only 61 percent of the health facilities reported having a selection policy restricted to the EDL, while 39 percent of the facilities used the list as well as other drugs not included.

Availability of the EDL was found to be very low at district pharmacies, where only 64 percent of the sites surveyed reported having the document. Although CAMERWA provides only essential drugs, facilities of the public sector often buy drugs through the private sector, where essential and non-essential drugs can be acquired. Therefore, the lack of knowledge of the EDL and the existing gaps of the health system create an environment where the use of only quality essential drugs cannot be guaranteed.

Discussion

The national EDL document should be available at all facilities, and appropriate training should be provided, including the essential drug concept and reasons for sticking to the EDL for drug selection and procurement. At the same time, the health system should incorporate adequate regulations to guarantee that only essential drugs are provided through the public sector.

Further study is needed to address the distribution between EDL and non-EDL supplies and the choices made by different facilities to use drugs not included in the list.

Pharmacy Supply Management: Financing

Acquisition of health commodities by health facilities requires financing. Health system financing is the process by which revenues are collected, accumulated in fund pools, and allocated to specific health actions. Methods of generating funds for a health system may include taxation of the general population, user fees, community financing schemes, public and private health insurance systems, and donations from international donors or the private sector.

Financing of health commodities for HIV/AIDS treatment programs is a critical area of concern because HIV/AIDS can be fatal if patients are not treated, HIV/AIDS is a chronic disease requiring lifelong treatment, and interruption of treatment for patients on ART can result in treatment failure and the development of drug resistance, which has implications for future usefulness of drug regimens for a larger population.

Findings

The survey asked about relevant financing practices of health facilities. Eighty-five percent of health facilities reported charging for medical consultation, 85 percent reported charging for laboratory tests, and all facilities (100 percent) reported charging for pharmacy service. With respect to how revenues collected are used, 93 percent of health facilities reported using the revenue to purchase pharmaceuticals.

Most health facilities in Rwanda have revolving funds that were created with seed funding from a World Bank grant. In principle, seed funding is supposed to be used by health facilities to purchase pharmaceuticals. Charging patients for items purchased at the pharmacy then generates funding to replenish the fund and then, by charging sufficient prices for pharmaceuticals, the fund is able to replenish itself into the future (at least for the cost of the items and perhaps a markup).

More than half of health facilities (67 percent) reported aiming to recover 100 percent of costs through their cost-recovery program. Fourteen percent of facilities aimed to recover part of the costs incurred by the health facilities through the cost-recovery program. Six percent of facilities did not state specific-cost recovery goals for the cost-recovery program.

It appears that among facilities surveyed a high proportion of costs for various elements of health care delivery are recovered through the cost-recovery program. Eighty percent of consultation costs are recovered, 80 percent of costs for laboratory services, and 97 percent of pharmacy costs.

Among the different levels of the health system, more health facilities appear to achieve partial cost recovery (92 percent) for major areas of service delivery (consultation, antenatal care, laboratory services, and pharmacy services), followed by district hospitals (84 percent) and then

by referral hospitals (67 percent). Only 43 percent of district pharmacies reported achieving partial cost-recovery for pharmaceutical supplies.

Most facilities reported using revenues generated through the cost-recovery program to replenish pharmaceutical supplies. However, although 89 percent of facilities reported that revenues from the cost-recovery program were used to replenish pharmaceuticals, 49 percent of all facilities reported using revenues collected for other costs, such as salaries. Thirteen percent of all facilities reported having separate budgets established for ARVs.

Table 15 summarizes findings with respect to cost-recovery knowledge and practices at health facilities.

Table 15. Cost-Recovery in the Public and Mission Health Facilities

Level	All Facilities Surveyed	Level of Care				N
		Referral Hospital	District Pharmacy	District Hospital	Health Center	
Goal of cost-recovery is 100%	67%	33%	93%	59%	62%	N = 49
Goal of cost-recovery is partial	14%	67%	0%	12%	23%	N = 49
Goal of cost-recovery is unknown	6%	0%	0%	18%	0%	N = 49
Cost-recovery covers (partially) consultation	80%	67%	N/A	82%	92%	N = 35
Cost-recovery covers (partially) laboratory	80%	67%	N/A	82%	92%	N = 35
Cost-recovery covers (partially) antenatal care	80%	67%	N/A	82%	92%	N = 35
Cost-recovery covers (partially) pharmacy services	97%	67%	43%	82%	92%	N = 49
Cost recovery covers other services	6%	33%	N/A	0%	8%	N = 35
Revenues of drug sales are used for stock replacements	89%	100%	93%	71%	100%	N = 49
Revenues of drug sales are used for other services	49%	100%	43%	41%	46%	N = 49
Special budget for ARVs	13%	67%	7%	12%	8%	N = 49

N/A = not applicable

Discussion

From Table 16, it was observed that about one-fifth of the surveyed health facilities do not know the goals of the cost-recovery program. Of facilities, 89 percent use revenues from drug sales to buy more drugs. Cost-recovery for pharmaceutical services has a higher rate than for other services for which patients are charged, such as consultation, antenatal care, and laboratory services. Most health facilities indicate that pharmacy revenues are used to replenish

pharmaceuticals. However, almost half of the health facilities reported that revenues are used to pay for overhead such as salaries.

The assessment did not investigate in detail mechanisms of price setting and whether the price of drugs that patients have to pay is reasonable according to the context and to global indicators. The gaps in drug regulation affecting the pharmaceutical sector are likely to affect price setting at the different levels of health care. Further investigation is needed to better understand the environment of price setting in the public sector and the regulatory mechanisms that could be established.

Pharmacy Supply Management: Procurement

Procedures

Procurement is the process of acquiring supplies, including these obtained by purchase, donation, and manufacture.[13] In Rwanda, two national nonprofit wholesalers—CAMERWA (a nonprofit private foundation established in 1998) and BUFMAR (a nonprofit mission-sector foundation established in 1977)—procure most health commodities. About 20 private sector wholesalers procure both essential and nonessential drugs, as well as medical supplies and laboratory reagents. However, private sector pharmacies were not included in the survey. Fewer drugs, medical supplies, and laboratory reagents are supplied through donations. These tend to be limited to vertical programs such as tuberculosis (drugs) and HIV/AIDS (drugs and test kits). Referral hospitals often procure their drugs by direct importation.

In principle, district pharmacies and referral hospitals are supposed to procure drugs from CAMERWA. District hospitals and health centers in turn procure supplies from district pharmacies. In reality, however, health facilities are free to choose whether to procure from district pharmacies or directly from CAMERWA, from BUFMAR, or from private sector wholesalers.

The survey found that rather than purchasing health commodities from district pharmacies, health facilities are also buying directly from CAMERWA, BUFMAR, and private sector wholesalers. In-depth interviews revealed that facilities prefer to purchase from CAMERWA and resort to purchasing from BUFMAR and finally from the private sector depending on the availability of commodities and the selling prices.

[13] Management Sciences for Health. 1997. Managing Drug Supply, 2nd ed. West Hartford, CT: Kumarian Press, p. 182.

Table 16. Sources of Health Commodity Procurement among Health Facilities Surveyed

Level N = 49	All Facilities Surveyed	Level of Care			
		Referral Hospital	District Pharmacy	District Hospital	Health Center
District pharmacy	45%	0%	N/A	71%	77%
CAMERWA	71%	100%	100%	65%	69%
BUFMAR	71%	33%	100%	65%	69%
Private sector	69%	100%	64%	76%	69%
Donations	45%	67%	29%	41%	69%
Direct importation	2%	33%	0%	0%	0%
Other	2%	0%	0%	6%	0%

N/A = not applicable

More than half (54 percent) of health facilities reported that the final decision on procuring health commodities rests with the person in charge of the pharmacy. Two-thirds of the facilities surveyed (63 percent) reported procuring health commodities on a monthly basis. Most district pharmacies, district hospitals, and health centers fell into this category. However, no referral hospitals reported procuring on a monthly basis. Rather, one facility reported procuring bi-monthly, one procured on a quarterly basis, and one facility procured twice a year. More than one-third (40 percent) reported procuring commodities as the need arose.

In interviews, facilities reported that ordering from the private sector was done as an emergency measure arising from unanticipated stock-outs at major suppliers such as CAMERWA. Health facilities would also order from the private sector when seeking to purchase items not on the Rwanda EDL.

Facilities were asked what methods they used for ordering commodities from CAMERWA. Facilities use a combination of methods for placing orders. Most facilities reported traveling to CAMERWA to place orders in person (61 percent). Less frequently, orders are placed by fax (18 percent). Seldom are they placed by telephone or regular mail. No orders are placed by electronic mail.

Table 17. Order Mechanisms to CAMERWA

Order Mechanism N = 49	All Facilities Surveyed	Level of Care			
		Referral Hospital	District Pharmacy	District Hospital	Health Center
Orders placed in person	57%	33%	86%	47%	54%
Orders placed by fax	16%	33%	29%	18%	0%
Orders placed by telephone	8%	0%	14%	12%	0%
Orders mailed to CAMERWA	4%	0%	7%	6%	0%
Orders placed electronically	4%	0%	0%	0%	0%

More than half (57 percent) of health facilities mentioned they found differences between the quoted prices of items and the ultimate selling price. This problem arises from frequent fluctuations in foreign exchange rates. Since most facilities pay for and pick up items in person, they are forced to buy less than they intended to buy because of insufficient cash on hand (as a general rule, CAMERWA does not extend credit to health facilities).

Quality Assurance and Quality Control

As a consequence of the lack of drug regulation in the country, the pharmaceutical system in Rwanda has not established any quality assurance (QA) and quality control (QC) systems at national level. On its own initiative, CAMERWA is the only agency that has, to a certain extent, established a mechanism to assure the quality of the products that are provided, with respect to some aspects of pre- and postqualification procedures. CAMERWA has permanent staff in charge of following up different steps of the QA/QC system, such as prequalification of manufacturers and providers, prequalification of drugs, control of storage conditions (cold, light protection, etc.) inside the stores, and regularly sending samples of drugs to be analyzed out of the country.

Facilities were asked about the quality of health commodities purchased. Health facilities reported variation in quality of items purchased. About 10 percent of the facilities reported having received products from CAMERWA with close expiry dates. Two percent of facilities surveyed reported having received poor-quality products from BUFMAR, although none reported having received expired products from this supplier.

Almost all health facilities expressed concern about the quality of products purchased from the private sector, and 16 percent of facilities reported having received poor quality products from this group of suppliers.

Referral hospitals procure some of their drugs by direct importation. Even though there are regulations regarding importation processes in general, drug registration has still not been established, and there are no clear mechanisms that control the quality of products not procured through CAMERWA.

Distribution of Health Commodities

The main pharmaceutical wholesalers (CAMERWA, BUFMAR, and most for-profit private sector suppliers) are based in Rwanda's capital city of Kigali, which is physically located in the center of the country. None of these organizations has distributors outside of the capital.[14]

Rwanda's relatively good network of roads linking all the major cities of its 12 provinces with the capital facilitates transportation of health commodities. However, a number of roads outside of this main road network that lead to peripheral areas are in poor condition, and some are virtually impassable, particularly at times of the year such as the rainy seasons. Although most

[14] In the Plan of Action CAMERWA 2004, instituting a decentralized distribution system, with two new regional warehouses operational by the end of 2004, is proposed. However, the concept has not yet been studied in detail and no decision has been made (discussion during the debriefing meeting at CAMERWA December 18, 2003).

health facilities can reach Kigali by road within four hours, some health facilities require a six- to eight-hour drive to reach Kigali (particularly those in the southwestern region).

Transportation of health commodities is further hampered by the fact that health facilities have to collect their commodities from suppliers in Kigali. Only 55 percent of the health facilities surveyed reported having their own vehicles. This means that 45 percent of health facilities depend on external means of transportation to place and pick up orders for health commodity purchases.

Almost all health facilities declared that the vehicles they use for transportation of health commodities are not appropriate for this purpose. Many facilities use the health facility's ambulance or ordinary 4 x 4 vehicles for this purpose. Since these vehicles are usually used for other purposes (transportation of other passengers, personal shopping, purchase of other items for the health facility) when driven to Kigali, storage space for health commodity purchases is often insufficient. Vehicles are not equipped to meet any cold chain requirements that may arise for certain health commodities.

Discussion

CAMERWA is known to be the main supplier of health facilities, with a market share of about 80 percent. Donations are for open-ended treatment (such as ARVs) and for those supplies used in vertical programs. Most orders are placed in person by facilities and picked up on the same day. Facilities have to send people to Kigali to procure from CAMERWA; neither CAMERWA nor other vendors transport health commodities to peripheral health facilities.

Health facilities procure commodities not only from district pharmacies but also directly from CAMERWA, BUFMAR, and private sector wholesalers. District pharmacies also procure drugs from the private sector. Anecdotal evidence shows that health facilities prefer to circumvent the district pharmacies. However, buying directly from CAMERWA rather than district pharmacies creates added expenses for health facilities, such as transportation to Kigali. The role and image of district pharmacies should be improved in order to achieve a simpler and more efficient procurement system for health centers and district hospitals.

Because facilities tend not to communicate with CAMERWA and other vendors before traveling to Kigali to procure health commodities, they sometimes arrive to find that commodity prices have changed significantly because of foreign exchange fluctuations (often prices have increased), forcing them to buy less for the facility than initially intended.

CAMERWA and BUFMAR experience stock-outs of key essential drugs and health commodities that contribute to shortages at the facility level. A more efficient quantification system should be implemented at CAMERWA to prevent stock-outs of health commodities that affect the overall health system. This improvement is especially critical if ART is to be introduced on a large scale in Rwanda. A communication system that allows clients to easily access information on availability of supplies and prices is also recommended to be established.

Even though CAMERWA has established a system to assure the quality of the products they procure, QA/QC systems should not rely in individual initiatives. A national system is needed to control not only the quality of the products from CAMERWA but also from BUFMAR, private sector and public hospitals that often import specialties directly to the health sites.

Drug Use

Rational use of drugs should be evaluated in more detail because the success of antiretroviral treatment programs requires that systems be in place to ensure rational and consistent prescription and dispensing practices, as well as effective and complete drug counseling. Such systems should incorporate adherence monitoring and systems for detecting and monitoring adverse drug reactions. Appropriate measures should also be in place to ensure confidentiality of patients.

Prescribing

It is recommended that pharmacies routinely monitor drug prescribing practices—not only as part of stock management, but also to reinforce the pharmacist's role in the clinical management of patients. Drug prescribing practices are monitored through the use of forms and registers, which should be audited at regular intervals. A standardized registration system is essential for monitoring prescriptions for ARVs and other drugs used in HIV/AIDS programs.

Forty-one percent of health facilities reported having a system of registers for recording prescriptions. Only 5 percent of health facilities routinely monitor the dispenser. Only 9 percent of health facilities reported having a system to monitor drug use in the patient.

Dispensing

Dispensing drugs requires an adequate space to ensure confidential communication between the dispenser and the patient. The ability to ensure confidentiality is particularly important for ART programs, given the negative stigma still associated with HIV infection in Rwanda.

The survey asked facilities whether adequate space existed for dispensing drugs and whether the dispensing room was configured to promote patient confidentiality. Most facilities (75 percent) reported having a separate room for dispensing. Although the majority (57 percent) of facilities felt that dispensing space was adequate, only 21 percent of district pharmacies and 38 percent of health centers concurred. Only one-third (34 percent) of facilities felt that the dispensing room was configured so as to ensure patient confidentiality.

Although it is not a common practice, 18 percent of health facilities reported repacking drugs for patient use.

Table 18. Adequacy of Dispensing Room in Facilities Surveyed

Level N = 49	National Total	Level of Care			
		Referral Hospital	District Pharmacy	District Hospital	Health Center
Dispensing room is adequate in space	57%	67%	21%	59%	38%
Dispensing room is adequate in confidentiality	34%	33%	0%	29%	46%
Patient is informed about drug use	71%	67%	0%	76%	77%

Discussion

Traditionally, the role of the dispenser in counseling and drug information has been neglected in many countries. However, aspects concerning adherence to treatment and adverse drug reactions have become a priority in providing quality ART. In this environment, there is the risk of understanding counseling as a need related to AIDS patients only, and to implement better dispensing practices just for patients who are under ART, which could increase the social marginalization and stigma, and erode the positive impact of scaling up ART.

Infrastructure upgrades might be necessary in many facilities in order to provide an adequate environment of confidentiality between dispenser and patient, which, although especially important for AIDS patients, is essential for providing good health care in general. At the same time, good dispensing practices will require the development of SOPs and tools, and dispensers should be trained in their use.

SOPs and tools should also be developed and dispensers trained in monitoring patients, including adverse drug reactions, according to national policies and guidelines.

Summary of Findings and Recommendations

The assessment examined key components of the public pharmaceutical system in Rwanda. These components included policies and legal framework, human resources, pharmaceutical supply management systems, and drug use.

The following matrix summarizes findings and outlines recommendations for strengthening the pharmaceutical sector in support of antiretroviral treatment programs.

Pharmacy Sector Findings and Recommendations

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
POLICIES, STANDARDS, AND LEGAL FRAMEWORK		
• A draft of the National Drug Policy (NDP) approved by a working group was to have been approved by the Ministry in 2004.	• The text of the NDP has not yet been approved and gazetted by the Ministry of Health.	• Approval, publication, and implementation of the Rwandan NDP should be advocated.
• Two laws concerning pharmaceutical regulations have been approved. The law of Pharmaceutical Art published in 1999 provides a legal framework for pharmaceutical activities. The law Art de Guérir published in 2000 covers aspects of medical, dental, and pharmaceutical care.	• No ministerial Instructions related to the existing laws have been gazetted	• Elaboration and publication of Ministerial Instructions for existing laws should be advocated.
• The Directorate of Pharmacy under the Ministry of Health has been established to develop, coordinate, and regulate policies affecting the pharmaceutical sector.	• The Directorate of Pharmacy does not cover all key pharmaceutical areas. • Only three pharmacists are integrated into the staff composing the Directorate of Pharmacy.	• An expanded and agreed range of activities should be assigned to the Directorate of Pharmacy in coordination and with support of other stakeholders. • Staff working at the Directorate of Pharmacy should be upgraded.
• A National Commission for drug registration is contemplated under the law of Pharmaceutical Art.	• The National Commission has not yet been established and no registration procedures have been developed.	• Drug registration regulations should be articulated and a regulatory body established following the law of Pharmaceutical Art.
• The Rwandan Essential Drugs List (EDL) has been available since 1997 and was updated in 2002 by a workshop group. Essential drugs, medical supplies, and lab reagents are included. • A Rwandan National Formulary has been developed.	• There is no established EDL commission in charge of reviewing the EDL, and standard procedures to update the list are not in place.	• A permanent EDL body should be established and standard procedures put in place to ensure periodical reviews and updates.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
• Standard operating procedures (SOPs) and guidelines for diagnosis, treatment, and care of HIV/AIDS, sexually transmitted infections (STIs), opportunistic infections (OIs), and other diseases have been developed by different ministerial directorates and programs.	• Existing SOPs and guidelines are insufficiently available at health facilities. Availability of HIV/AIDS, OI, and STI-related documents was notably low at district pharmacies. • Several fields of health commodity management are not covered by policy guidelines and SOPs, including dispensing, counseling, and manufacturing practices.	• An efficient distribution system for SOPs and guidelines should be established to ensure the availability of key documents at all pharmaceutical sites. Causes for unavailability of documents in district pharmacies might be further investigated and recommendations provided. Available SOPs for antiretroviral (ARV) drugs might require adaptation to each pharmacy level. • SOPs and guidelines should be developed for all areas of health commodity management.
• SOPs for importing drugs are already in place. • CAMERWA (Centrale d'Achat des Médicaments Essentiels du Rwanda) has established its own quality assurance system for drugs by sending samples to Niger to be analyzed.	• National quality assurance and quality control systems have not been established. (The only controls to ensure drug quality are performed through CAMERWA.)	• A quality assurance system to ensure quality of drugs should be established at national level and implemented at pharmaceutical sites. Some quality-control operations could be established within the country according to specific needs, technical capacity, and available resources.
• An Information Division is in place at the Directorate of Pharmacy.	• The Information Division is not fully operational. There is not a Pharmaceutical Information Center.	• A Pharmaceutical Information Center should be established, and communication channels should be developed to ensure accessibility of information to health professionals.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
HUMAN RESOURCES		
Staffing levels • Number of staff working at pharmacy sites seems to be sufficient for current activities, since no problems were reported in the survey. • Most of the pharmacy sites surveyed employed at least one A2 or A3 nurse. • Pharmacists are available at public referral hospitals.	**Staffing levels** • Pharmacy staff members tend to move to other services (within or outside the same facility). A possible cause reported is that nurses prefer to perform the job for which they have been formally trained, even when in-service pharmaceutical training has been provided. • No pharmacists are available at regional or district levels of public health because they are concentrated at referral hospitals and in the private sector. • More than a quarter of the sites surveyed employ "other staff" (no nurse or pharmacists) at the pharmacy.	**Staffing levels** • The need to hire additional staff should be considered and quantified with the introduction of antiretroviral therapy (ART). • Mobility of pharmacy staff should be further investigated and strategies implemented to promote greater stability. • Possibilities should be explored to compensate for the lack of pharmacists at regional and district levels, such as supervisory visits to offer qualified technical support (flying pharmacists). • Further investigation is needed to evaluate the appropriateness of using "other staff" at pharmacies according to tasks assigned and level of training.
Training • Pharmaceutical studies can be performed inside the country. The National University of Rwanda in Butare offers a curriculum for obtaining a pharmacy degree. • Several training institutions for nurses exist in Rwanda. • A large number of staff involved in pharmacy services has received additional training.	**Training** • Pharmacy degree is the only preservice training available in pharmacy because other pharmaceutical cadres (such as pharmacy assistants or technicians) do not exist and the nursing curriculum does not cover drug supply management issues. • Pharmacy preservice training does not include HIV/AIDS-related commodity management.	**Training** • Introducing some aspects related to drug supply management into the nursing curriculum should be considered to compensate for deficiencies of pharmacy staff. • Involving the Directorate of Pharmacy to some degree in updating the pharmacy university curriculum might be considered to identify new areas of training, such as the introduction of HIV/AIDS-related commodity management.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
	• A remarkable proportion of the pharmacies surveyed reported the need for more training in general pharmaceutical issues as well as in HIV/AIDS-related topics. Some of the requested areas of training include drug procurement, rational drug use, store management, prevention and treatment of OIs, use and monitoring of ARV drugs, and management information systems for ART.	• A strategic plan should be developed to ensure continuing education and information in all pharmaceutical sites. • The introduction of SOPs and tools at all levels of pharmacy management should be accompanied by adequate training. • Training in key areas related to the management of drug supplies, including store management, quantification of needs, and drug use, should be provided. • The introduction of ART and ARV drugs requires training in key areas such as storage precautions for ARV drugs, confidentiality, and rational use of drugs.
PHARMACEUTCIAL SUPPLY MANAGEMENT SYSTEMS		
Infrastructure and equipment • Guidelines for pharmacy space have been developed by the Ministry of Health. • The building conditions of most of the pharmacies surveyed (adequacy of walls, roofs, windows, and doors) were acceptable. • Most of the pharmacies surveyed had at least minimum equipment necessary for good storage practice (shelves, pallets, and cabinets). • Available functioning refrigerators were found in 73% of the sites.	**Infrastructure and equipment** • The adequacy of some pharmacy spaces is sometimes limited by the fact that most areas actually used for pharmaceutical services were not built for that purpose. Moreover, the use of the guidelines for pharmacy space is not always feasible because most pharmacy areas were built before the publication of the guidelines. • Overall, half of the health facilities require a better outfit of storage places to meet the minimum requirements for storing drugs, which also apply to ARVs.	**Infrastructure and equipment** • Adequacy of building conditions should be ensured for all pharmacies, including maintenance of walls and roofs, ventilation and protection from light, and security through lockable windows and doors. Options to address shortages of storage spaces should be explored according to context and needs. • Adequate equipment should be ensured in all pharmacies for general and controlled drugs, through maintenance of equipment and furniture and/or provision of lockable cabinets for controlled drugs and ARVs.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
	• Of the facilities surveyed, 56% have storage spaces smaller than standard requirements. • Less than half of the facilities reported having a reliable supply of electricity. • Part of the equipment available is in poor condition. Lockable cabinets to ensure secure storage of ARVs and controlled drugs are not always in place. • Some pharmacies did not have a refrigerator or it was not functioning	• Shortages of electricity should be investigated and recommendations made according to particular contexts. • Provision of refrigerators should be considered for the facilities where refrigerators were unavailable or nonfunctioning.
Store management • Most (86%) of the pharmacies surveyed reported using inventory controls, mainly by physical stock control.	**Store management** • Basic errors in bin cards and stock keeping were found during visits. Stock balances were frequently not recorded. • Lack of training was not the only cause of inadequate inventory control because even some trained staff did not perform good controls. One supervisor identified deficiencies in planning supervisory visits as a problem needing technical support. • Controlled drugs are not always locked and stored in a separate area in accordance with standard recommendations of security. • Waste management was not assessed in detail, but only 59% of the facilities reported having a functioning incinerator.	**Store management** • Guidelines for store management (including SOPs for inventory control and security of controlled drugs and ARVs) should be developed at central level, and distributed and implemented at regional and district levels. The involvement and coordination of the Directorate of Pharmacy, CAMERWA, and other stakeholders is recommended. • Minimum standards and indicators for monitoring commodity management implementation should be agreed upon and established. • Adequate training for pharmacy staff and supervisors should accompany the implementation of guidelines, SOPs, and monitoring systems.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
		• Further investigation is needed to address whether pharmacy waste management is adequate. The development of SOPs for pharmacy waste management should be considered.
Availability of drugs • None of the referral hospitals surveyed reported having experienced stock-outs of essential drugs from tracer list. • Only 37% overall of the facilities surveyed reported having experienced shortages of essential drugs.	**Availability of drugs** • Only 25% of the facilities surveyed provided information about availability of drugs and stock-outs. Poor record keeping seemed to be the cause of lack of information. • No clear patterns emerged from the survey with respect to the kinds of drugs that are more likely to suffer stock-outs.	**Availability of drugs** • Further investigation is needed to evaluate shortages of drugs at facility levels. Improvements in inventory control should be accompanied by the establishment of a recording/reporting mechanism to monitor availability of drugs.
Quantification • All facilities surveyed reported using main parameters to quantify drug needs (95% of facilities use historical consumption and 14% use epidemiological data). • Quantification is mainly carried out by the person in charge of the pharmacy.	**Quantification** • No SOPs for quantification have been developed. • Inadequate inventory control hampers adequate quantification systems. • Some important parameters needed for accurate quantification, such as days out of stock or morbidity data, were insufficiently or never applied. • Training in quantification methods is insufficient.	**Quantification** • SOPs for quantification should be developed at central level and implemented at all facilities, in coordination with the Directorate of Pharmacy, CAMERWA, and other stakeholders. • Adequate training should accompany the introduction of SOPs. • A system to monitor adequacy of quantification systems should be established because the scaling up of ART programs might affect the accuracy of the current estimates.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
Selection • All pharmacies surveyed use the Essential Drug List as a reference for drug procurement.	**Selection** • 39% of the pharmacies purchase drugs not listed in the Essential Drug List, through the private sector. • The EDL document was available in only 76% of the sites surveyed (64% for district pharmacies).	**Selection** • The establishment of a national EDL committee is recommended to ensure that the EDL is responsive to the health needs of Rwanda (see Policies, Standards, and Legal Framework). • Therapeutic committees are recommended to be established in all health facilities to agree on selection of drugs and protocols, according to context and national guidelines.
Financing • All surveyed facilities have a cost-recovery system in place. • Most surveyed facilities have as an objective full cost-recovery for the pharmaceutical services. • Some pharmaceutical sites have independent financial management and use a special bank account.	**Financing** • Most public and mission health facilities declare that part of the pharmaceutical services revenue is spent for other services, mainly salaries. • Price setting is insufficiently based on economic principles. • Collected revenue (cash available) is insufficient for full replacement of items or for expanding the range items. • External audits are infrequently conducted.	**Financing** • Developing guidelines and providing training in financial management for staff in charge of pharmacies are recommended. • The introduction of flexible payment conditions at CAMERWA should be considered to enhance cost-effective procurement. • Mechanisms to improve independent financial management for pharmacies should be enforced, for example through the use of independent and controlled bank accounts. • A system of external audits and technical support should be implemented.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
Procurement and distribution • Facilities can obtain health supplies from CAMERWA, BUFMAR (Bureau des Formations Médicales Agréées du Rwanda), district pharmacies, and the private sector. CAMERWA, however, is the most important supplier. Some drugs, medical supplies, and reagents are supplied through donations (vertical programs for tuberculosis and HIV/AIDS). • Orders can be placed at CAMERWA in person, by fax, telephone, and e-mail. About 61% of the facilities place the orders in person. • Two-thirds of pharmaceutical sites reported procuring health commodities on a monthly basis. • Rwanda has a relatively well-developed road network. • Over half of the public and mission health facilities owned means of transport.	**Procurement and distribution** • Procurement through district pharmacies is not efficient enough, and pharmacies do often need to reach the capital to get supplies. • Of the facilities, 40% reported procuring commodities as need arose, more often than on a monthly basis. • The main pharmaceutical wholesalers are based in Kigali and they do not have distributors outside the capital, which especially affects distant facilities. • Transportation means are often inadequate for health commodities and frequently shared with other purposes. • CAMERWA and BUFMAR experience stock-outs of essential drugs and health commodities, which contribute to shortages at facility level.	**Procurement and distribution** • The role and efficacy of the district pharmacies should be reinforced in order to improve efficiency of transportation and distribution. Other possibilities to improve problems related to transportation and distribution should be explored • Technical assistance should be provided to CAMERWA for establishing more accurate quantification and procurement systems, including for those health commodities related to HIV/AIDS. • A communication system between suppliers and facilities should be established to ensure efficiency in the procurement cycle. • The procurement of health commodities through vertical programs is recommended to be coordinated and integrated within the national procurement systems.
DRUG USE		
Prescribing and dispensing • Half of the health facilities have a system to record and register prescriptions. • Most health facilities have a separate dispensing room.	**Prescribing and dispensing** • Prescription monitoring has not been widely established. • The dispensing room is not always adequate. Inadequacy of space was reported in 57% of the facilities and inadequacy for confidentiality in 37%. • Around one-third of the patients were not informed about drug use by the dispenser.	**Prescribing and dispensing** • A standardized system for recording prescriptions should be developed and established. Special procedures to record ART should be implemented to ensure confidentiality. • Infrastructure upgrades might be required at some health facilities.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
		• SOPs and guidelines for good dispensing and counseling practices, including those related to HIV/AIDS, should be developed at central level, implemented at all facilities, and accompanied by training. • The creation of patient drug information leaflets in Kinya-rwanda should be explored to enhance rational use of drugs in general and especially of ARVs.

LABORATORY SECTOR SURVEY

Organization of the Laboratory Sector

Several organs comprise the national public health laboratory system in Rwanda. The laboratory system functions under the coordination of the National Reference Laboratories, which are based in Kigali. The National Reference Laboratories comprise two bodies: the National HIV Reference Laboratories and the National Public Health Laboratories.

Built in 1996, the National HIV Reference Laboratory is responsible for—

- Research
- Drug resistance surveillance
- Development of national VCT protocols for districts and health centers
- Sentinel surveillance

In addition, the national HIV laboratory—

- Complements activities of district hospitals and health centers because there are no specialized HIV labs at lower levels of the health system, including performing tests not available at other levels of the health system, such as—
  - ELISAs
  - Western blot tests
  - CD4 testing
  - Viral load tests
  - Cultures
- Coordinates training of persons involved in VCT at different levels of the health system in collaboration with TRAC
- Coordinates QA/QC for the whole country (taking 10 percent of all positive tests and 10 percent of all negative tests for validation) in collaboration with TRAC
- Performs inspections of district and health center labs

Although the mandate of the national HIV laboratory has been established, only some of the activities described are well under way, while others are in the process of being established, and still others are being phased out. The national HIV laboratory was performing HIV tests for the general public at the time of the assessment, but national-level discussions had been under way in 2003 to streamline operations of this laboratory so that it would cease performing such tests for the general public and focus instead on research and surveillance.

A QA/QC system currently exists only for diagnostic tests done for specific diseases considered to be of public health significance. These diseases include malaria, tuberculosis, HIV, and meningitis.

HIV drug-resistance surveillance is being established with donor assistance and will operate in-country when it is in place. The National HIV Reference Laboratory has a functioning system for inspecting laboratories; it inspects both district and health-center level laboratories and has the power to close or discipline laboratories found not to be in compliance with nationally established laboratory standards.

Although independent of the National HIV Reference Laboratory, TRAC works closely with this body as the technical and implementing arm of the fight against HIV/AIDS to—

- Formulate and implement national VCT and PMTCT policy as well as policy for treatment of HIV-infected patients
- Coordinate surveillance on HIV
- Coordinate PMTCT and VCT activities

The National Public Health Laboratory (NPHL) is responsible for defining and enforcing laboratory standards and for carrying out surveillance for all diseases other than HIV/AIDS. Additionally, the NPHL supervises all peripheral laboratories in the country. Supervision is organized in a pyramidal fashion, whereby the NPHL conducts periodic supervisory visits to district-level facilities, and district health authorities in turn supervise health centers laboratories.

Laboratories in both health centers and district hospitals are required to submit bi-weekly statistics to district health supervisors, who pass this information up the health system chain. Information submitted is mainly epidemiological and is used by the Ministry of Health's Department of Epidemiology in monitoring changes in disease patterns and detecting epidemics. This information is submitted on a standardized form used by the entire health system. Other information, however, does not appear to be used in the management of laboratories; stock levels of key commodities, for example, are submitted through this information system. The National HIV Reference Laboratory (in coordination with TRAC) does track the available of key commodities used in the VCT and PMTCT programs.

Established with assistance from the Luxembourg Cooperation, the Atelier National de Maintenance was created as an autonomous body within the Ministry of Health to coordinate a mechanism for repairing hospital equipment throughout Rwanda's health system. Technicians were trained at the Atelier and subsequently installed at all district hospitals in the health system, where they were to be responsible for maintaining and repairing laboratory equipment in both district hospitals and health centers in corresponding districts.

The Atelier was to be the national repair center of last resort for repairing equipment too complex for the district-based technicians to handle. However, lack of standardization of laboratory equipment throughout the Rwandan health system has resulted in the inability of these technicians to repair all equipment and consequently contributed to the continued presence of nonfunctioning laboratory equipment within Rwanda's public health system.

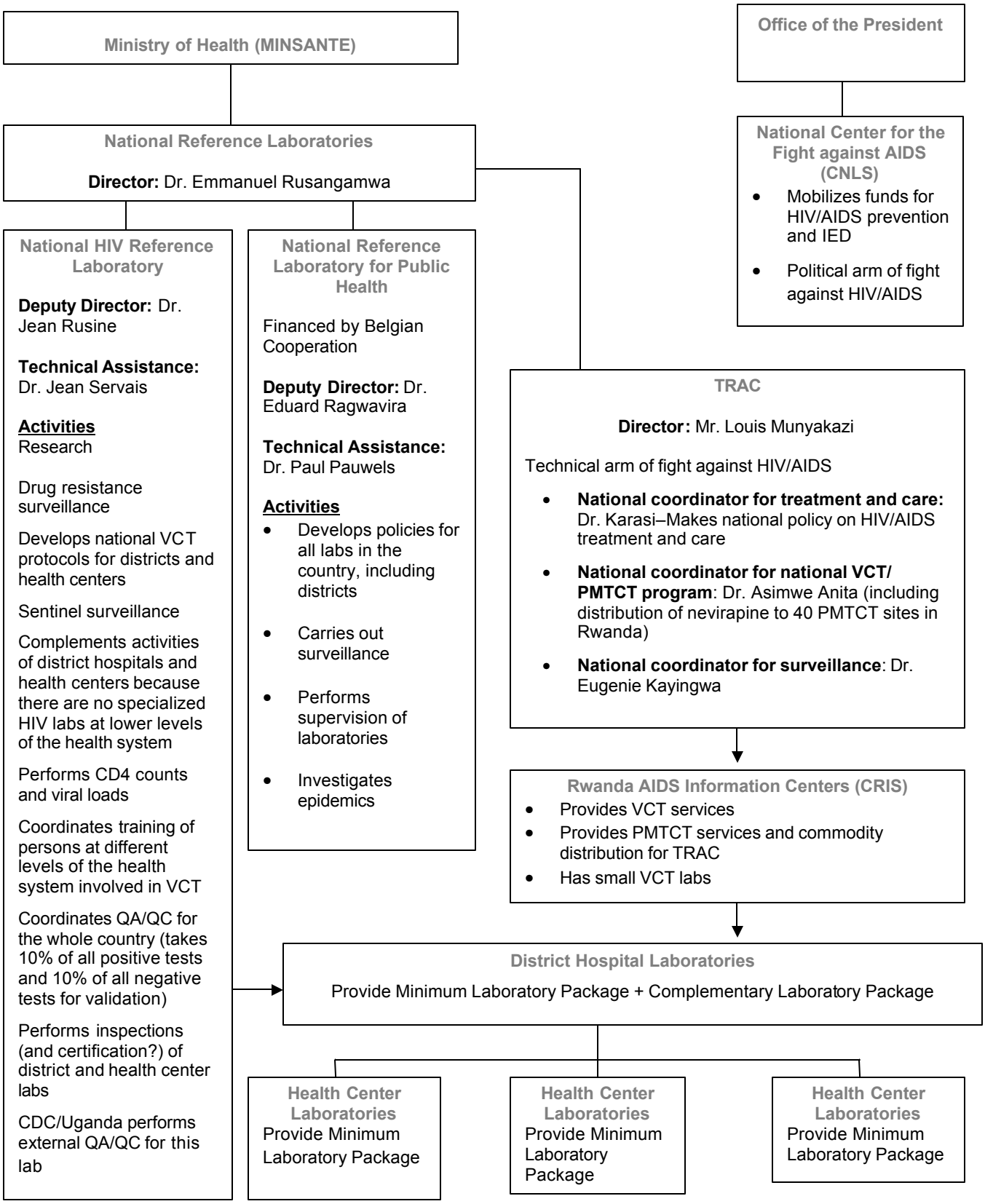

Figure 4. Structure of the health care system in Rwanda

Laboratory Sector Survey

Policies and Standards

National policies provide a framework for laboratories and laboratory workers to perform laboratory services appropriate to each level of the health system. Standards establish norms for the content and quality of these services.

Findings

Policies important to the functioning of ART programs include—

- National testing protocols for VCT
- Testing protocols specifically developed for monitoring HIV/AIDS treatment
- Guidelines for PMTCT of HIV/AIDS
- Guidelines for postexposure prophylaxis (PEP)
- Guidelines for universal precautions
- Guidelines on staffing levels and required training

Such national guidelines developed for Rwanda include the *Guide pour la prise en charge clinique et thérapeutique de l'infection à VIH chez l'adulte et l'enfant* and the *Guide d'utilisation des médicaments antirétroviraux chez l'adulte et l'enfant.* This second guideline was revised in 2002. Both guidelines were disseminated to 34 district hospitals during a training on antiretroviral treatment held for clinical staff in November 2003.[15]

Standards important to laboratory management of patients on antiretroviral therapy include—

- Laboratory tests the health system should perform
- Equipment that should be available
- Reagents and supplies that should be available for HIV/AIDS testing and treatment

This section focuses on laboratory tests to be performed by the health system; equipment, reagents, and supplies are dealt with in another section.

Laboratory tests required for patients on antiretrovirals include baseline tests (performed before starting treatment) and monitoring tests. Some monitoring tests will include tests to monitor adverse drug reactions, depending on the regimen being used by the patient.

The WHO has defined four categories of laboratory tests for antiretroviral therapy programs in low-resource settings: absolute minimum tests, basic recommended tests, desirable tests, and optional tests, summarized in Annex 4.[16] Small-scale ART programs in sub-Saharan Africa have created standard protocols for comprehensive laboratory testing.[17] The laboratory testing

[15] Dr. Pierre Rugimbanya, Coordinator for Quality Assurance, National Reference Laboratories of Rwanda, 2004.
[16] WHO. 2002. *Scaling up Antiretroviral Therapy in Resource-Limited Settings: Guidelines for a Public Health Approach*, Geneva: WHO, pp. 17–18.
[17] See Mombasa ART program.

protocol will depend on the antiretroviral combination selected, as well as the epidemiology of that particular country.

In early 2003, the government of Rwanda began the process of defining a minimum package of laboratory tests that should be available at each level of the health system, which is summarized in Annex 5. However, a study carried out for the Rwanda Ministry of Health in 2001 found that only 22 percent of all district hospitals in the country were capable of providing this minimum package. Although this minimum package covers some of the tests required in an ART program, it does not cover all the tests.

The Rwanda ART assessment sought to determine whether key tests for monitoring patients on ART are currently performed by the health facilities surveyed. Key tests include HIV serology, basic hematological tests, basic biochemistry tests, and some basic microbiological tests.

Of laboratories surveyed, 31 (86 percent) reported doing rapid-HIV testing. Only 2 (5 percent) laboratories reported carrying out ELISA. The majority of laboratories assessed (63 percent) do complete blood counts, and 72 percent perform white blood cell counts and differentials.

With respect to biochemistry testing, all laboratories perform urinalysis testing. However, very few do other biochemistry testing. Only 25 percent do alanine transaminases (ALT) and aspartate transaminases (AST), with even fewer doing bilirubin (19 percent), ALP (14 percent), and total protein tests (14 percent). Only 25 percent perform serum creatinine, and 17 percent perform urea and electrolytes. With respect to microbiology, all labs perform thick blood smears, urine sediment, and stool testing for ova and parasites. The majority of labs perform thin blood films (83 percent), gram staining (97 percent), AFB sputum smears (94 percent), and syphilis testing (89 percent).

Table 19. Percentage of Public and Mission Health Facility Laboratories Surveyed Performing Key Tests for ART Monitoring

Facility	Rapid HIV	CBC	LFT/ ALT	LFT/ AST	Urea and Electrolytes	Urinalysis (Albumin, Protein, Glucose)	Serum Amylase	CD 4	Viral Load
Health Center (N = 15)	80%	46%	0%	0%	0%	100%	0%	0%	0%
District Hospital (N = 18)	88%	72%	38%	38%	22% (N=4)	100%	11%	0%	0%
Referral Hospital (N = 3)	100%	100%	67%	67%	67%	100%	67%	66%	33%

Discussion

The fact that the Rwanda Ministry of Health has developed guidelines on HIV/AIDS treatment and care is very positive. The draft laboratory standards for testing provide a foundation on which to build comprehensive standards for HIV/AIDS laboratory testing for all levels of the health system.

The assessment found that health facilities in Rwanda are not providing the minimum package of laboratory tests for ART monitoring defined by the WHO. Even health centers, which have the fewest required tests, are barely providing hematological testing. Another survey showed that district laboratories appear far from being able to provide the minimum package defined by the Ministry of Health, let along the package defined specifically for ART by the WHO. This gap at the district level is of particular concern because this level of the health system would be expected to perform the bulk of the more complex laboratory tests for ART monitoring.

Various reasons may cause institutions not to provide laboratory tests appropriate to the level of the health system. Some institutions lack the appropriate equipment or reagents. One referral institution revealed that the only biochemistry tests it was able to perform were urine tests using reagent strips because it had neither the equipment nor reagents to do others. Such equipment and supplies had been requisitioned two years ago, but the items had not been procured to date, and the reasons for this situation were not clear. The institution was therefore obliged to send its patients to other referral institutions for these tests.[18]

Cost of tests may encourage facilities to substitute one methodology with another. The assessment team learned that the same facility had stopped doing ELISA tests a few years ago and had instead switched to rapid tests because they were cheaper and easier to administer. Test kits and reagents for VCT were being provided by a project at the time of the follow-up visit for the survey, but we were told this supply would not continue beyond 2003, and it was not clear what plans the institution had in place to be able to continue providing HIV rapid-testing services.

Some institutions do not perform certain laboratory tests because they do not have staff capable of running tests or using certain equipment. In addition to not having appropriate equipment and reagents, at least one district hospital reported having equipment but no staff sufficiently trained to be able to run biochemistry tests.[19]

Human Resources:Staffing Levels

Optimal functioning of a laboratory requires sufficient staffing. Insufficient staffing levels can result in increased mistakes in processing of tests, which leads to inaccurate, unreliable results. Safety measures in the laboratory may be ignored as a result of insufficient staffing. WHO recommends that at least two staff members be available for health center laboratories and at

[18] Interview with key informant.
[19] Interview with key informant.

least six for district level laboratories.[20] However, these numbers must be revised according to the workload of the laboratory. It is recommended that the workload of each section of a laboratory be monitored every three months or so and staffing adjusted accordingly.[21]

Findings

When asked how many staff members worked at each laboratory, the referral level hospitals reported 18, 31, and 57 staff respectively. The average number of people working in district hospital laboratories was 4, ranging from 2 to 10 lab staff members. The average number of staff working in health centers was 3, with a range of 1 to 8 staff.

Rwanda has three levels of qualifications for laboratory personnel. The highest qualification of A0 requires a university degree in laboratory sciences. The next level is A1, which requires a high school diploma plus two or three years of postsecondary education. A2-level laboratory staff require a high school diploma. For general laboratory work, an appropriate level of training is a high school diploma coupled with a certificate in medical technology. For specialized laboratory work (e.g., serology), laboratory workers should have a high school diploma, a certificate in medical technology, and additional training (e.g., higher diploma) in the area of specialization.

Rwanda previously had an A3 category of laboratory staff (three years of high school education), but this category is being phased out as A3 staff are being upgraded to A2. Some laboratories also use personnel without formal qualifications in laboratory sciences who have been trained on the job.[22] (Details on staff distribution in the surveyed areas are provided in Annex 6.)

At each level of the health system, between 40 percent and 57 percent of lab staff come from the A2 cadre. Interestingly, the distribution of Al and A2 lab staff among the three levels of the health system is skewed toward the referral and district facilities. Forty percent of A2 staff work at district hospitals, almost as many (39 percent) work at referral hospitals, and only 21 percent work at health centers. The distribution of the few A1 staff is even more uneven among the three levels of the health system. Of A1 lab staff, 57 percent works at referral level facilities, 38 percent works at district hospitals, and 5 percent works at health centers. A3 staff are distributed more evenly. Among the three levels of the health **care** system, the largest percentage of staff trained onsite was found at health centers.

When asked what the major obstacles were to both general laboratory work and HIV/AIDS-related lab work, a number of facilities said that staff shortages were a major obstacle in both areas: 61 percent of district hospital laboratories said staff shortages were a major obstacle to functioning of the lab, as did 33 percent of health centers. Of district hospital laboratories,

[20] Laboratory technician plus lab assistant are recommended for a health center laboratory. For a district level laboratory, qualified medical pathologist or microbiologist, lab technician with diploma in medical technology, lab assistants, lab attendants, cleaner, clerk/storekeeper are recommended. WHO, Guidelines on standard operating procedures for Microbiology, http://w3.whosea.org/microbio/index.htm, and Guidelines on standard operating procedures for Haematology, http://w3.whosea.org/haem/index.htm.

[21] M. Cheesbrough. 1998. *District Laboratory Practice in Tropical Countries.* Part 1. Cambridge: Cambridge University Press.

[22] Emmanuel Rusanganwe, Director, National Reference Labaratory.

72 percent said staff shortages were a major obstacle to doing HIV/AIDS-related lab work, and 33 percent of health centers responded similarly.

Discussion

Laboratories across the health system appear to be understaffed, particularly at the district level. It is not clear, however, if understaffing is caused by an insufficient number of laboratory personnel throughout the country, or if it is a problem of poor distribution of laboratory personnel according to laboratory workload.

The distribution of different cadres of lab staff with more formal training is skewed toward the referral and district levels of the health system, particularly for A1 and A2 staff. It is not clear whether this results from planning by the Ministry of Health for this distribution, based on determination of staffing levels according to workload, or from a preference of A1 and A2 staff to be stationed at higher levels of the health system. However, perceived staffing shortages indicated by district hospitals and health centers in responses to questionnaires raises the question whether redistribution of existing staff within the health system according to average workload of facilities might be part of the solution for addressing understaffing among laboratories.

Comments from a key informant shed some light on the impact of this understaffing. One referral institution reported having to absorb the workload from another referral hospital that does not have the capacity to do biochemistry tests. As a result, turnaround time for test results has increased, causing patients to have to return on subsequent days for results, thus increasing their transportation costs. Laboratory staff are working many more hours as a result, and the institution has therefore resorted to limiting the number of samples it will process per day for certain tests to maintain a reasonable pace of work.

Table 20. Laboratory Staffing in Health Facilities, by Level of the Health System

Staff Level	Referral Hospital	District Hospital	Health Center
Lab A0	4%	0%	0%
Lab A1	12%	11%	2%
Lab A2	40%	57%	48%
Lab A3	8%	9%	13%
Trained onsite	6%	14%	23%
Physicians	2%	0%	0%
Scientists	0%	1%	0%
Nurses	0%	3%	0%
Health Assistant	0%	1%	4%
Aide Lab Technician	0%	1%	4%
Support Staff	23%	0%	4%
Cleaners	5%	3%	2%

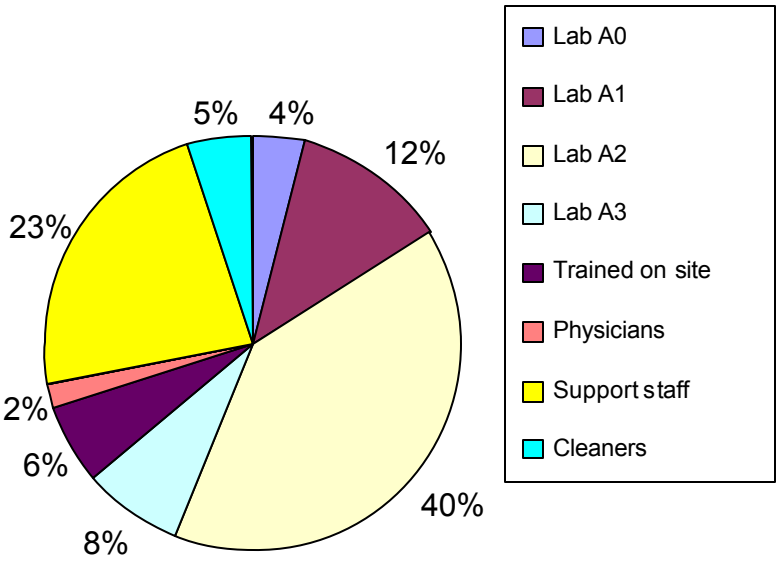

Figure 5. Distribution of staff, referral hospital

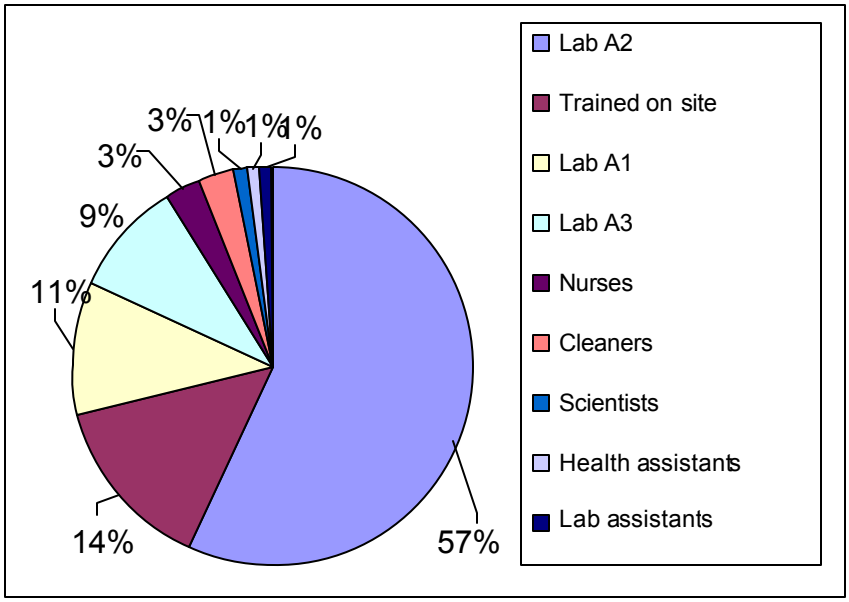

Figure 6. Distribution of staff, district hospital

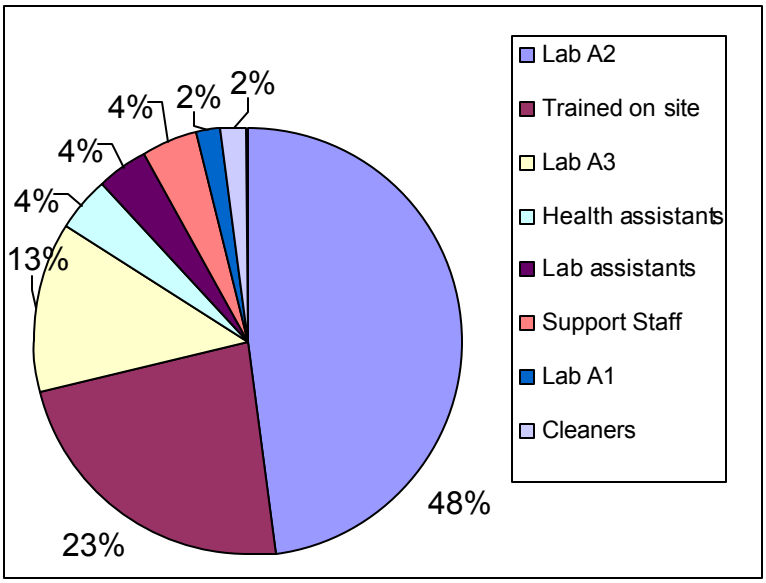

Figure 7. Distribution of staff, health center

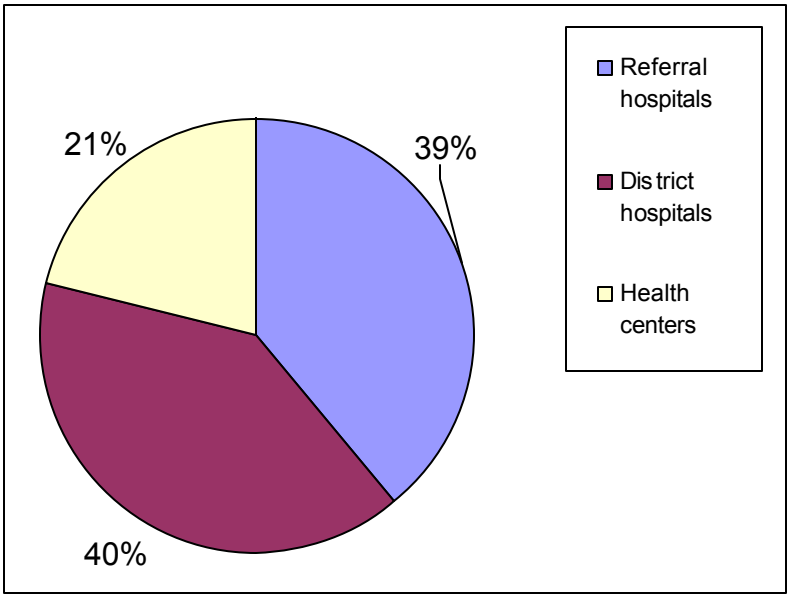

Figure 8. Distribution of A2 staff

Human Resources: Training

Poorly or insufficiently trained laboratory personnel can be costly to an ART program, because they can contribute to errors in test results, to the need for repeating lab tests, to shortened life of laboratory equipment caused by improper use, and to additional time needed for supervising staff. Laboratory monitoring for HIV/AIDS treatment requires personnel who are specifically trained in performing laboratory tests for monitoring patients with the disease. Such training

should include biochemistry, hematology, and microbiology testing, as well as HIV rapid and/or ELISA testing.

Beyond initial training, laboratory workers need to maintain competence in laboratory techniques. This is best achieved through continuing education in the form of onsite, competency-based training.[23] To perform well laboratory staff also require adequate supervision in the course of their work.

Findings

In addition to looking at formal educational backgrounds of laboratory staff described in the previous section, the assessment also sought to determine the extent to which laboratory workers had recent training in laboratory techniques related to HIV detection and HIV/AIDS treatment monitoring. When asked whether there had been any training in HIV/AIDS monitoring within the past two years or HIV laboratory monitoring, 56 percent reported receiving training in the past two years in HIV testing (rapid or ELISA testing). Three percent of labs reported having received training in hematology testing and 33 percent received training in microbiology. None reported having received training in biochemistry within the past two years.

Table 21. Training Received within Past Two Years, by Level of the Health System

System Level	HIV Testing (Rapid or ELISA)	Hematology	Biochemistry	Other Microbiology (Other than HIV)	CD4 Testing	Viral Load Testing
Referral N = 3	33%	0%	0%	33%	33%	0%
District N = 18	72%	0%	0%	27%	0%	0%
Health Center N = 15	40%	6%	0%	47%	0%	0%

Respondents were asked what additional training they felt they needed in relation to laboratory monitoring for HIV/AIDS. Among all facilities, 8 percent felt they needed additional training in rapid HIV testing; 19 percent felt training was needed in ELISA testing; 11 percent felt training was needed in biochemistry; 33 percent felt that training was needed in CD-4 testing, 31 percent in viral load testing, and 14 percent said they needed training on laboratory testing related to ARV treatment in general. The breakdown by level of the health system is provided in Table 22.

[23] M. Cheesbrough. 1998.

Table 22. Laboratory Training Needed, by Level of the Health System

System Level	Rapid HIV Testing	ELISA Testing	Hematology	Biochemistry	CD4 Testing	Viral Load Testing
Referral N = 3	0%	0%	0%	0%	66%	66%
District N = 18	5.5%	27%	5.5%	11%	33%	27%
Health Center N = 15	13%	13%	13%	13%	26%	26%

When asked whether reference materials were available in the laboratory, 25 percent reported having access to the national syllabus for HIV testing. Fifty-eight percent have access to the WHO series *Manuel de Techniques pour le Laboratoire*. Twenty-five percent have access to other textbooks or manuals. Twenty-two percent have access to continuing education courses, 22 percent have access to technical staff updates, and 14 percent have access to visiting experts.

Discussion

On the positive side, it appears that most labs surveyed (60 percent) have staff with at least minimum qualifications, which includes at least a high school education.

For laboratory work, practical experience and familiarity with commonly used reagents and equipment can be more important than level of formal training. One lab staff member at a district hospital pointed out that that the number of years of training of staff is not necessarily the most important factor—work experience is. In his experience, an A2 person with several years of work experience would be equally or more useful in a laboratory than an A1 person with no work experience.

ART monitoring, however, will require new tests or techniques to be introduced to laboratories, skills that A2 staff may not have been able to acquire through their work experience. Therefore, in increasing or redistributing staffing levels, skills and knowledge of staff should be factored in as well as strategies to improve staffing.[24] Additionally, new tests required for ART monitoring will have to be incorporated into preservice training curricula for both A2 and A1 laboratory staff.

Staff will need to be trained in handling equipment and reagents that are actually being used in the public sector institutions. This is sometimes a challenge because donation of equipment that does not follow nationally developed guidelines can create variation in the equipment found in different laboratories.

One key informant described how the budget process in government was an impediment to obtaining new lab staff. New staff can be requested only at the end of a fiscal year, when the new fiscal year budget is being drawn up. When there are unanticipated increases in workload at other

[24] Key informant interview, December 2003.

times of the fiscal year, public institutions have little recourse for acquiring additional staff. Furthermore, there are restrictions on hiring staff on short-term contracts.[25]

Areas in which training has not been provided within the past two years appear to be hematology and biochemistry, followed by microbiology (other than HIV testing). Interestingly, lab staff members do not seem to feel that they necessarily need training in those areas and seemed to think training was needed only in tests done at the referral level, such as CD4 counts and viral load testing.

The low frequency of recent training in these areas implies that many health facilities may not be capable of responding to the laboratory monitoring needs for an ART program. Basic hematological testing is supposed to be provided at all levels of the health system in Rwanda; basic biochemistry testing is supposed to be provided at district health facilities according to Rwanda's draft national laboratory policy. All levels of the health system are required to be capable of performing basic microbiological testing.

Infrastructure and Equipment

Water, Electricity, and Telecommunications

WHO recommends that, at minimum, any laboratory should have electricity and running water.[26] Of laboratories surveyed, 67 percent reported having electricity and having running water. Fifty-six percent reported having a telephone, 8 percent reported having a fax, and 8 percent reported having e-mail; 8 percent had some other form of communication, such as a radio. Also important but not examined in the survey was availability and quality of space, which has implications for security and capacity to absorb new or larger equipment. Quality of space, such as appropriateness of building materials, has implications for ability of staff to perform work optimally.

Availability of Basic Equipment

Laboratory equipment required for laboratory monitoring for HIV/AIDS treatment programs depends on the level of the health system. Essential lab equipment recommended by the WHO for all developing country peripheral laboratories includes microscopes, centrifuge, balance (if reagents are made in the lab), refrigerator for keeping reagents, a water bath, a hand tally counter or differential counter, and a photometer or colorimeter (for accurate determination of hemoglobin levels and for some biochemistry tests). Health center labs need their own autoclave for sterilizing instruments. A hot-air oven is needed for drying glassware and for use in conjunction with the autoclave. A deionizer or water still is needed to demineralize water. Glassware and other small equipment, such as a staining trough, thermometer, timers, and burners are also necessary.[27] All this equipment is used in HIV/AIDS laboratory monitoring.

[25] Key informant interview, December, 2003.
[26] WHO, Guidelines on standard operating procedures for Microbiology, http://w3.whosea.org/microbio/index.htm, and Guidelines on standard operating procedures for Haematology, http://w3.whosea.org/haem/index.htm.
[27] WHO. 2003. *Manual of Basic Techniques for a Health Laboratory,* 2nd ed.Geneva: WHO.

Of labs surveyed, 86 percent reported having a microscope at the time of the survey. Ninety-two percent reported having a centrifuge, 19 percent reported having an autoclave, 36 percent reported having a refrigerator, 28 percent reported having a balance, 36 percent reported having a water bath, 14 percent reported having a hot-air oven, and 39 percent reported having a colorimeter, photometer, or spectrophotometer.

Table 23. Availability of Equipment in Laboratory Sector

Equipment	Percentage of Labs with Equipment Available
Centrifuge	92%
Microscope	86%
Colorimeter, photometer, or spectrophotometer	39%
Water bath	36%
Refrigerator	36%
Balance	28%
Autoclave	19%
Hot air oven	14%

Main equipment suppliers to district hospitals were reported to be CAMERWA, BUFMAR, and KIPHARMA. The main suppliers of equipment to health centers were reported to be FHI/IMPACT, KIPHARMA, BUFMAR, and AFRICHEM.

Equipment Management

Laboratories cannot function effectively when their equipment malfunctions or breaks down completely. Of laboratories surveyed, 47 percent reported equipment breakdowns within the past six months. Only 19 percent of laboratories reported having service agreements for all laboratory equipment.

District hospitals reported equipment such as microscopes, distillers, hemaglobimeters, photometers, spectrophotometers, centrifuges, and autoclaves not working. One laboratory mentioned that equipment had been sent to a workshop at a referral hospital in Kigali for repairs only to return with the same problem. Microscopes and centrifuges were the most common type of equipment reported to be malfunctioning at the time of the survey. One laboratory reported that both types of equipment had been nonfunctioning for months.

Discussion

It appears from the assessment that many labs lack basic equipment and almost half of laboratories surveyed have malfunctioning equipment.

Comments within the questionnaires revealed that no well-functioning functioning national or regional mechanism seems to exist for repairing laboratory equipment when it breaks. Several labs mentioned that they had arrangements with the District Health Authority for fixing broken equipment. Others mentioned that broken equipment was fixed by the Atelier National based in

Kigali. However, the technicians in those institutions at times did not have the capacity to fix broken equipment.

Equipment management policy is critical in laboratories. Lack of such a policy results in inappropriate equipment being purchased, inappropriate donations being accepted, incomplete procurement (lack of spare parts for example), and equipment damage from improper training of staff or lack of maintenance—all of which hamper the inability of the lab to provide uninterrupted, quality services.[28]

Interviews conducted during preparation of survey instruments gave insight into some effects of malfunctioning equipment. When one referral-level facility experienced equipment breakdown, no CD4 tests were done in the entire country for several weeks. In this instance, difficulty in repairing equipment stemmed from the reality that Rwanda has few technicians capable of maintaining and repairing laboratory equipment.[29]

Laboratory Supply Management: Inventory Management

Efficient management of laboratory inventory (reagents, consumable supplies, and equipment) is critical to ensuring that quality, uninterrupted laboratory services are provided. The variety of equipment, reagents, and supplies used in the laboratory creates many challenges to their management.

Indicators used to assess the state of inventory management in laboratories surveyed were the availability of basic reagents and supplies, the occurrence of stock-outs, and the presence of expired items in the laboratory. Although the assessment did not go into detail about how inventory management systems are organized in different laboratories in Rwanda, it did seek to understand some elements of organization of inventory management, particularly those linked to information systems.

Availability of Basic Reagents and Supplies

A list of key reagents and supplies necessary for ART programs was defined for the purposes of the assessment based on existing lists from various institutions.[30] Although the list in the questionnaire was extensive, only key items from this list were selected for analysis. See the Annex 7 for this list.

The national HIV testing protocol for Rwanda uses Determine™ HIV 1/2 as the initial test, followed by UNIGOLD™ for confirmation of all positive tests, with Capillus™ HIV as a tie-breaker. Sixty-nine percent of labs reported having Determine test kits in stock and 61 percent reported having reagents for the kits. Fifty-three percent reported having UNIGOLD test kits in stock and 50 percent reported having reagents for UNIGOLD kits. Sixty-nine percent of labs reported having Capillus test kits in stock and 61 percent reported having reagents for these tests.

[28] M. Cheesbrough. 1998.
[29] Key informant interview conducted in July 2003.
[30] Institutions included WHO/AFRO, which has developed a list of basic laboratory supplies and equipment for HIV testing, and Coast General Hospital, Mombasa, Kenya, where RPM Plus has been providing technical assistance for pharmaceutical and laboratory management of an ART program.

Sixty-one percent of labs reported having lancets in stock, and 28 percent reported having blotting paper in stock. These data should be viewed in the context that 86 percent of labs surveyed reported they routinely perform rapid HIV testing.

In the area of hematology testing, 17 percent of labs reported having plain vacutainers, and 78 percent reported having Giemsa stain, a key reagent in staining slides in hematology tests.

With respect to biochemistry testing, only six labs (17 percent) reported having urine reagent strips. Eleven labs (31 percent) reported having purple-top EDTA vacutainers. Only six labs (17 percent) reported having reagent kits for performing alanine aminotransferase and aspartate aminotransferase tests—two key liver function tests. Of labs surveyed, 22 percent reported having test kits for serum creatinine (for assessing renal function) and four labs (11 percent) reported having test kits for bilirubin. Only six labs (17 percent) had the test kits for serum glucose testing, and three labs (8 percent) had the test kit for serum amylase in stock at the time of the survey.

In terms of other key supplies, 26 labs (72 percent) reported having gloves in stock, 15 labs (42 percent) reported having micropipettes, 11 labs (31 percent) had tips in stock for use with the micropipettes, and 7 labs (19 percent) reported having biohazard bags for disposal of laboratory waste in stock.

Table 24. Availability of Consumables and Reagents in Laboratory Sector

Item	Percentage of Facilities with Item
Giemsa stain	78%
Gloves	72%
Micropipettes	42%
Tips	31%
EDTA vacutainers	31%
Test kit for serum creatinine	22%
Biohazard bags	19%
Plain vacutainers	17%
Test kits for ALT	17%
Test kits for AST	17%
Test kit for serum glucose	17%
Test kit for bilirubin	11%
Test kit for serum amylase	8%

Stock-Outs

The occurrence of stock-outs is an important indicator of poor inventory management. Stock-outs of reagents and supplies translate into the inability of a laboratory to perform tests. Expired products among stocks also signal poor inventory management, and their use in the laboratory can compromise laboratory test results.

When asked about the occurrence of reagent and consumable supply stock-outs during the past six months, 39 percent of laboratories surveyed reported stock-outs of HIV test kits, and 42 percent reported stock-outs of reagents within the same period.

The following sections provide more information about the nature of stock-outs reported in the questionnaire.

Referral Hospitals

Referral hospitals reported stock-outs of ELISA test kits, ELISA reagents, Western Blot assays, antibiotic discs, media cultures, and CD4 reagents. One referral hospital explained that the stock-outs for test kits were caused by lack of funds. This hospital eventually chose to stop doing ELISAs for confirmation of positive tests because of high cost and instead switched to using rapid test kits.[31] Reagents were reported to be supplied to referral hospitals by BUFMAR, KIPHARMA, and Africhem.

One referral hospital reported stock-outs of consumables but did not specify which. Suppliers of consumables to referral hospitals are reported as CAMERWA, KIPHARMA, and Africhem. A key informant interview conducted in preparation for the assessment revealed that one referral-level laboratory experienced frequent shortages because of bureaucratic procedures. At that time, all orders exceeding 3 million Rwandan francs had to be done through the National Tender Board, which had a minimum lead time of about a month. Shortages resulted because most orders placed by the laboratory usually surpassed this amount.[32]

District Hospitals

District hospitals reported stock-outs for all three test kits used in the national VCT protocol. At least three district hospitals experienced stock-outs of UNIGOLD test kits, while another reported experiencing stock-outs of all three (UNIGOLD, Determine, and Capillus) test kits over the past six months. HIV test kits are provided by IMPACT/Rwanda, TRAC, ARBEF, GTZ, and KIPHARMA.

Stock-outs were reported for reagents for urea and electrolytes and for amylase test kits. Stock-outs occurred for reagents necessary for equipment such as electrolyte and hematology analyzers. At least three laboratories reported stock-outs for reagents used in liver function tests. At least one district hospital reported having had no biochemistry reagents in the past six-month period. Main suppliers of reagents to district hospitals are KIPHARMA, Africhem, and BUFMAR, with CAMERWA supplying only a couple of facilities.

With respect to consumables, stock-outs of gloves were reported by one facility. Suppliers of consumables include BUFMAR, CAMERWA, KIPHARMA, and the Société Ruando-Suisse.

[31] Follow-up interview with referral hospital, December 2003.
[32] Key informant interview, July 2003.

Health Centers

The most commonly mentioned HIV test kit to be out of stock was UNIGOLD. Suppliers of HIV kits to health centers include FHI/IMPACT, UNICEF, and TRAC. Suppliers of reagents to health centers include BUFMAR, the District Health Authority, CAMERWA, and KIPHARMA.

With respect to consumables, one health center laboratory mentioned having been sent the wrong type of tips—blue instead of yellow. Suppliers of consumables to health centers include FHI/IMPACT, CAMERWA, BUFMAR, KIPHARMA.

Expired Products

Forty-two percent of data collectors reported seeing expired products in the laboratory at the time of the visit when the questionnaire was administered. When asked why they kept expired products in stock during follow-up interviews, a couple of the laboratories said those products were not used, since they were known to be expired. Others said they were waiting to destroy the expired products, but were keeping them on shelves with unexpired products in the meantime.

Tools of Inventory Management

The main instruments for managing inventory in the laboratory are policies, procedures, and forms. Policies provide the framework for a laboratory inventory management system and generally cover—

- Where inventory is kept and under what climatic and security conditions
- Which information is to be recorded
- Which tools should be used for recording information (e.g., stock cards, forms)
- Which reports are to be generated periodically

The questionnaire did not specifically ask about storage methods, although it is notable that only 17 percent of labs reported having temperature controls (air conditioning or fans). With respect to inventory management tools, it was directly observed during follow-up of data collection that although some laboratories surveyed had excellent inventory management systems that included separation of like items in storage areas, bin cards for each storage item, and up-to-date records on movement of stock, other laboratories had partial or nonfunctioning inventory management systems. Only 36 percent of labs reported having refrigerators on the premises for storage of reagents and specimens.

When asked who carried out quantification of reagents, supplies, and equipment for the laboratory, 92 percent of laboratories replied that the laboratory manager was responsible. Fifty-eight percent of labs reported that the laboratory manager placed orders for commodities used in operating the laboratory, and 83 percent of labs reported that the laboratory manager prioritized what to order if the budget did not allow all needed items to be purchased.

Laboratory Supply Management: Information Systems

Systematic and standardized collection and review of information is required for efficient laboratory management. Standardization of forms for requesting and reporting laboratory results assists in the interpretation of test results and in the comparison of laboratory results over time.[33]

Standard information collected on tests performed and resources used in laboratories assists in managing inventory and ensuring that adequate laboratory supplies are available. When information is properly stored and made available to external evaluators, its standardization also allows for assessment of the quality of laboratory services. On a larger scale, laboratory information that is aggregated at the central level of a health system can be used to assess the performance of the health system and to point out areas for improvement.

Tools commonly used to collect and report patient information in laboratory work include—[34]

- Request forms used by health providers to request laboratory tests
- Report forms used by the laboratory to report lab results to providers
- Laboratory registers, books kept within different sections of the laboratory with a permanent record of patient information and accompanying test results

Findings

The assessment requested information on a number of measures related to management information systems. Fifty-eight percent use standardized lab request forms and only 14 percent use standardized lab report forms. A few labs reported that lab request forms were used only for vertical programs. Where lab request forms are not used, requests for lab tests are commonly written on pieces of paper.

Eighty-one percent of labs reported having a system of laboratory registers; however, it was not clear whether registers existed for each section of the lab or if one register was used for the whole laboratory, as is known to be done in some laboratories in the country.

Sensitivity of patient information requires that a laboratory MIS incorporate measures to ensure confidentiality. These would include restricting access to information contained in laboratory forms and registers, and delivering results to health providers in sealed envelopes. Twenty-seven facilities (75 percent) reported having confidentiality measures in the laboratories**.**

Discussion

It is clear from the results that laboratories on all levels of the health system are lacking in some key supplies. When we look at the percentage of facilities that do HIV testing, we see that for all three types of tests, there is a gap in availability of test kits, and that in turn there is a gap in

[33] M. Cheesbrough. 1998.
[34] M. Cheesbrough. 1998.

availability of reagents for these test kits. Although these results could be a temporary phenomenon, stock-out data confirm that around 39 percent of labs surveyed had stock-outs of HIV test kits and reagents within the last six months, signaling that this problem could be chronic.

The results show that key supplies are lacking in all the main areas of the laboratory pertaining to ART monitoring—hematology, biochemistry, and microbiology. Furthermore, supplies to ensure the practice of universal precautions such as gloves and vacutainers are lacking.

Stock-outs are happening for a number of reasons. Facilities report that they are caused by lack of funding to buy supplies and because of bureaucratic procedures. Key informants also report that stock-outs sometimes occur because of inability of suppliers and even overseas manufacturers to meet local demand for items. Given the multiple suppliers involved in providing laboratory items, careful planning and supply chain management will need to accompany ART scale-up to ensure that all potential obstacles to supply availability are addressed.

District hospital labs are poorly equipped with basic supplies and reagents to carry out key biochemistry tests for ART monitoring. Of 18 district hospitals surveyed, 4 reported having EDTA vacutainers, 4 had ALT test kits, 4 had AST test kits, 7 had creatinine test kits, 3 had bilirubin test kits, 4 had serum glucose test kits, and one district hospital had test kits for performing serum amylase tests.

Inventory management practices are poor at laboratories surveyed, given that 42 percent had expired products. Because the presence of expired products is partly linked to lack of policies, procedures, or permission to dispose of expired products, the disposal of expired laboratory products may have to be addressed as part of strengthening laboratory management for ART.

Laboratory managers are heavily involved in quantifying and ordering products for the laboratory. Therefore, any training to strengthen commodity management in public laboratories should target this group.

Basic equipment to ensure proper storage of laboratory supplies is lacking at a number of laboratories, with temperature controls such as air conditioning and refrigerators for storing lab supplies requiring refrigeration lacking at most laboratories. Providing such equipment will be critical to ensure that optimal storage conditions exist at laboratories participating in ART laboratory monitoring.

There is clearly a need to standardize tools and procedures for recording and storing information among laboratories assessed, as there appears to be a wide variation in the forms used among laboratories. It is also not clear how that information collected is used and whether it is fed back to the laboratories it originates from to encourage them to improve their performance.

There also needs to be a closer look at developing standard measures to be followed to ensure patient confidentiality across all laboratories, because a number of laboratories reported not having such measures in place.

Laboratory Supply Management: Quality Assurance and Quality Control

In the context of laboratory management, QA is a system established to detect errors between the time specimens are collected and the time results are reported. The tools for promoting quality assurance in laboratories are collectively known as good laboratory practices, or GLP. [35]

Quality assurance is usually divided into three stages: preanalytical (during the specimen collection phase), analytical (during the laboratory testing phase), and postanalytical (during reporting and interpretation of test results).[36]

Good laboratory practice measures to promote quality assurance in a laboratory include—[37]

- Introducing and using SOPs
- Standardizing which tests the lab is to perform
- Having a system for referring tests not normally done in the lab to specialist labs
- Having an effective system for collecting, identifying, and transporting specimens
- Standardizing labeling of specimens
- Having standardized systems for recording and storing laboratory data
- Defining and implementing health and safety regulations, particularly universal precautions
- Standardizing supplies and equipment used in the laboratory
- Introducing and using equipment management policies and procedures
- Measuring and recording internal quality controls
- Postexposure prophylaxis

Standard Operating Procedures

The assessment looked at a few key elements of quality assurance and good laboratory practices. Standard operating procedures are written instructions that describe standard ways of doing things in the laboratory, including exactly how lab tests should be performed; how quality control should be done, for each test; and how equipment should be stored and maintained. Although 86 percent of laboratories reported having SOPs, and 72 percent say they use them all the time, this number decreased when labs where asked whether SOPs existed for specific areas

[35] Ibid.
[36] Ibid.
[37] Ibid.

of the laboratory. Twelve labs (33 percent) reported having SOPs for HIV testing, 6 percent for hematology, 28 percent for biochemistry, and 39 percent for microbiology.

Further investigation during the assessment revealed that laboratory staff have different interpretations of what is meant by SOPs, and some of the SOPs made available for examination at a couple of laboratories were found to be greatly outdated or incomplete. Almost half of the labs reported using SOPs from other sources that had not been specifically developed for that laboratory—39 percent reported using the WHO publication *Manual of Basic Techniques for a Health Laboratory* as SOPs.

An interview with the National Public Health Laboratories in July 2003 revealed that SOPs had been developed for health center–level laboratories in 1999 through a project funded by the Belgian Cooperation. These SOPs were used to train 260 health center–level laboratory staff, who were followed up and supervised for a two-year period. However, it is not clear to what extent those SOPs are still in use in these health centers.

Referral Systems

The assessment only asked about existence of referral systems in relation to CD4 and viral load tests. However, this question was frequently not answered within the questionnaire. The lack of answers raises the question whether individual laboratories have sufficient information about the rest of the health system to know how and where to refer patients for tests. One referral hospital that had no capacity for biochemistry and CD4 tests described how it collected samples and had them transferred for processing to laboratories that had the capacity to perform the needed tests. For such institutions, it would be important to examine and strengthen procedures used for storing and transporting samples and for receiving test results.

Handling of Specimens

The assessment asked about the existence of standardized procedures for handling specimens and standardized procedures for processing tests. Eighty-six percent of the labs assessed described a standard procedure followed in the laboratory for handling specimens. Sixty-four percent of labs described standardized labeling for specimens.

Universal Precautions

With respect to use of universal precautions in the laboratory, 83 percent of facilities reported having gloves available to staff, and 67 percent had gloves in use at the time of the visit.

Postexposure Prophylaxis

Seventeen percent of facilities reported having policies and procedures for PEP, and 14 percent reported providing antiretroviral medicines to staff suspected of having been exposed to HIV.

Measuring and Recording of Internal Quality Controls

Quality control or "internal" quality control is the part of QA that deals with control of errors during the actual performance of laboratory tests and the verification of test results. Internal quality control is usually carried out on a daily basis during routine laboratory work.[38]

The questionnaire asked whether a system of internal quality controls existed within the laboratory. Thirty-six percent of laboratories reported that a system of internal quality controls exists. However, this figure is questionable, because data collectors did not check whether internal quality controls were actually being recorded in registers or in a separate book, as is normally recommended as part of GLP. Only 14 percent of laboratories said that at least one laboratory staff had been trained in methods of internal quality control.

Twenty-five percent of laboratories said they had SOPs for internal quality controls. However, the data collectors were not qualified to check on these SOPs, so it is not clear if such systems and SOPs in fact exist. Only one laboratory reported having internal quality control records available to view at the time of the assessment.

System for External Quality Assessment

External quality assessment allows for evaluation of past performance of a laboratory on the various quality assurance measures and provides an opportunity to improve performance of the laboratory.[39] Eighty-three percent of laboratories surveyed reported having an external quality assessment system. Upon closer examination, however, these external QA activities seem largely confined to HIV testing (external QA done by TRAC) and tuberculosis testing (done by the National Tuberculosis Program). There does not appear to be a functioning external quality assessment system for other tests done in the laboratory surveyed.

Discussion

Overall, it appears that good laboratory practices are lacking among laboratories surveyed. SOPs do not exist in all facilities and they are not used consistently. One hundred percent of labs should have standardized procedures for handling specimens, but only 86 percent do, and 64 percent report having a standardized way of labeling specimens.

The finding that 14 percent of labs did not describe a standard procedure for handling specimens suggests that some labs could be experiencing compromised laboratory tests results as a result of this lack of standardization. Even for the labs that say they have standard procedures, experience with assessing labs in other countries shows that strong supervision must accompany written procedures, and this is often absent in many laboratories.

The absence of temperature controls in most laboratories suggests that depending on what type of testing is done in that lab, specimens may become compromised and give erroneous results. It

[38] Gabriel Mallapaty. 1999. The role of total quality management in raising the service quality of public health las in developing countries. Thesis, University of Derby.
[39] M. Cheesbrough. 1998.

is therefore important to address this problem by providing laboratories with appropriate temperature control mechanisms, particularly if samples are to be referred for testing at other levels of the health system and may require refrigeration before being transported to another lab.

Very few labs have postexposure prophylaxis policies and procedures, and even fewer provide medicines to their staff as part of the procedures. The creation and implementation of PEP policies and procedures should be addressed during the phase of readying facilities for ART programs.

Internal quality control systems barely exist among the labs surveyed. Only about one-third of labs report having a system of internal quality control, one-quarter had SOPs for internal quality control, and much fewer have at least person trained in internal quality control methods. This lack has serious implications for the reliability of test results. Introduction of ART will need to include strengthening the measuring and recording of test results. Additionally, the standard practice of universal precautions such as wearing of gloves will have to be reinforced.

Most labs do not have external quality assessment outside of vertical programs. Such a system will have to be introduced for public sector laboratories in the context of ART scale-up so as to measure performance of laboratories.

Laboratory Supply Management: Financing

Laboratories require financial resources to pay staff and buy resources used in providing laboratory services. Financing of laboratory services encompasses activities ranging from budgeting for the laboratory, generating financial resources to buy items for and pay staff working in the laboratory (e.g., through fees charged for lab tests), monitoring of operating costs and workload in the laboratory, and seeking and implementing measures to balance costs of running the laboratory with availability of financial inputs to operate the laboratory.

Findings

The questionnaire asked what the budget was for the laboratory. Only one laboratory provided information about the size of its budget, and several facilities reported not having access to this information. However, during key informant interviews, at least two referral labs reported that inadequate financing for the laboratory was a problem. One lab mentioned that the annual laboratory budget for reagents and supplies was not even 50 percent of what was required for the laboratory.

With respect to generation of resources for the lab, the questionnaire did ask whether patients paid for tests. Ninety-four percent of labs reported charging for tests. Forty-seven percent reported charging for HIV testing, 56 percent reported charging for complete blood counts, and 94 percent charge for parasitology tests.

Different levels of the health system behave differently in their use of financial resources generated from lab tests. In most health centers (93 percent), money generated by the lab goes

back to the facility, which in turn allocates the laboratory budget. Only 8 of 18 district hospitals (44 percent), however, followed this practice.

It is usually customary for such user fees to be used to buy supplies and equipment. Only 26 percent of health centers use money generated through lab user fees to buy supplies and equipment, compared to 38 percent of district hospitals.

Discussion

Laboratories surveyed do not appear to have enough money and do not appear to control the money they generate from lab tests. If the national ART program is to move toward financial sustainability, the funding levels of peripheral and referral-level laboratories may need to be reviewed and solutions found on the appropriate mix of funding sources to pay for laboratory supplies and equipment. Experience from other countries shows that introduction of ART programs can put significant additional demands on human and financial resources in laboratories within health institutions.

Implementing this recommendation may involve examining the internal practices of laboratories with respect to use of funds generated by laboratory tests. At the moment, it appears that many institutions use money generated by the laboratory tests for the general institutional budget.

Because respondents to the survey had little knowledge of the laboratory's budget, it is difficult to begin to make more specific recommendations on financing for laboratories other than to say that more specific information is needed on funding levels and internal allocation of laboratory funds within institutions.

Major Obstacles to HIV-Related Laboratory Functioning

The assessment included questions on the major perceived obstacles to the proper functioning of the laboratory in general and to carrying out HIV-related laboratory work in particular.

The top four obstacles perceived as hampering the functioning of the laboratory in general were—

- Lack of training (75 percent)
- Staff shortages (44 percent)
- Lack of supplies and stock (47 percent)
- Inadequate salary (36 percent)

The top four reported obstacles to HIV-related laboratory work were—

- Staff shortages (50 percent)
- Insufficient salary (47 percent)
- Lack of supplies and stock (44 percent)
- Inadequate training (36 percent) and lack of training (36 percent)

Discussion

Major obstacles to general laboratory functioning and to HIV-related laboratory functioning identified by facilities seem to overlap. They appear to be related mainly to human resources (numbers of staff, adequacy of training, and low salaries) and availability of supplies. These perceptions are consistent with the findings discussed earlier in this report on levels of human resources available to labs, on training carried out within the past two years, and on the availability of laboratory supplies. In particular, adequacy of training and availability of supplies will have to be addressed early in the introduction of ART programs at new sites.

Related elements such as numbers of staff and low salaries are more difficult to address, because they may involve complex procedures for redeploying staff and changing salary levels. They may also require significant financial resources that will have to be sought and may have to be addressed later on during the scale-up phase.

Summary of Findings and Recommendations

The assessment examined key components of the public laboratory system in Rwanda. These components included policies and standards, infrastructure, human resources, supply of equipment, reagents and laboratory consumables, quality assurance/quality control, referral systems, management information systems and financing.

The following matrix summarizes findings and outline recommendations for strengthening the laboratory sector in support of antiretroviral treatment programs.

Laboratory Sector Findings and Recommendations

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
POLICIES AND STANDARDS		
• A national laboratory policy is being developed. • The following HIV-related guidelines have laboratory elements, including some laboratory protocols, and are in use within the Rwanda laboratory system: ▪ *Guide pour la prise en charge clinique et thérapeutique de l'infection à VIH chez l'adulte et l'enfant* ▪ *Guide d'utilisation des médicaments antirétroviraux chez l'adulte et l'enfant* • Guidance exists on laboratory management for ART • Minimum packages of lab tests for different health care levels were defined by the government in early 2003.	• Policies and standards have not been fully disseminated to health facilities. • The minimum packages of tests do not include some of the tests required for ART monitoring according to the World Health Organization (WHO) guidelines. • Standard operating procedures (SOPs) exist but have not been tailored to individual laboratories. A number of facilities use generic SOPs.	• A national laboratory policy should be finalized by the central level, and distributed to labs at all levels of the health system. • National lab policies and standards on HIV/AIDS should be developed, finalized and distributed to all levels of the health system. These include lab policies and operations related to voluntary counseling and testing (VCT), prevention of mother-to-child transmission (PMTCT), and ART, as well as lists of essential reagents, supplies, and equipment. . A mechanism should be put in place to periodically update these documents. • The minimum package of tests for each lab level should be reviewed and ART tests should be included, integrated under national policies and standards for HIV/AIDS. • Model SOPs, including ART monitoring, should be developed, reviewed and updated at central level, and implemented at referral and district labs. Updated SOPs should be adapted at each lab facility according to context and needs.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
HUMAN RESOURCES		
Staffing levels • All laboratories surveyed have at least one qualified staff person (A0 to A3 level).	**Staffing levels** • Respondents report that staff shortage is one of top four obstacles to performing laboratory work. The average number of lab staff working at district hospitals is four, lower than the WHO recommendation of six. • Distribution of lab staff among the three levels of the health system is skewed, with the majority of A2 staff (biggest cadre) concentrated in referral and district labs (79% collectively) and the smallest percentage at the health centers (21%), which supports the finding that 33% of health centers complain that staffing shortages are an obstacle to doing laboratory work. • Both horizontal and vertical referral increase workload on certain laboratories, increasing the needs for staff. However, budgetary processes and government regulations preventing the hiring of temporary laboratory contract workers make it difficult to respond to these workload increases.	**Staffing levels** • Staffing levels and distribution of qualified staff should be reviewed according to current workload, range of tests performed, and expected increase in lab operations with the introduction and scaling up of ART. • Policies and procedures for redeploying staff should be reviewed in order to address staff shortages of overloaded laboratories. • Introducing automated lab equipment in key areas such as hematology and biochemistry is recommended to alleviate current workload in laboratories as well as in anticipation of increases in workload that may accompany scale-up of ART activities.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
Training • Training of lab staff is adequate to ensure the standards for lab operations, since all labs have at least one qualified staff member. The majority of labs have A2 level staff. • Trainings in HIV-related topics have been held within the past two years, particularly on rapid HIV testing.	**Training** • Most labs have not received training in other areas relevant to ART monitoring within the last two years, including hematology, biochemistry, and quality assurance.	**Training** • Basic training in ART monitoring should be provided, including training in standardized equipment and reagents according to revised minimum lab package. • A system of continuing education should be developed for laboratory staff at all levels of the health system. • In-service curriculum for training lab technicians should include standardized equipment, reagents, and procedures, and lab instructors should receive technical updates. • Develop list of key laboratory reference materials make it available at each level of the health system and in each laboratory.
INFRASTRUCTURE AND EQUIPMENT		
Electricity, running water, and communications • Two-thirds of labs assessed have electricity and running water.	**Electricity, running water, and communications** • Approximately one-third of the labs assessed reported not having running water or electricity, or having inconsistent supply of one or both. Insufficient supply of water and electricity hampers safety, quality of lab operations, and adequate storage conditions.	**Electricity, running water, and communications** • Further investigation is needed to address causes of unavailability of running water and electricity, and possible solutions should be explored.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
• Over half of labs surveyed have phones or access to telephone communication within the health institution where they operate.	• A large number of the labs surveyed (46%) do not have access to telephone within the health facility. This shortage could hamper the efficiency of lab referral mechanisms and supply management systems in support of ART programs.	• Further investigation is needed to address causes of unavailability of telephone access, and possible solutions should be explored (maintenance mechanisms for telephone lines, provision of mobile telephones, use of radios, etc.).
Availability and management of basic equipment	**Availability and management of basic equipment**	**Availability and management of basic equipment**
• Some mechanisms are in place to fix nonfunctioning equipment through the District Health Authority and the Atelier National. • Centrifuges and microscopes were available and functioning in most of the labs surveyed (92% and 86%, respectively).	• Maintenance mechanisms and staff capacity for fixing nonfunctioning equipment are often insufficient. Nonfunctioning equipment was found in some laboratories. • Some basic equipment, such as balances, autoclaves, and refrigerators, were not available in most of the laboratories.	• Maintenance mechanisms for key equipment should be established at district, regional, and national levels. Available structures (District Health Authority and the Atelier National) should be strengthened by improving communication links between peripheral and central levels and by supporting technical staff. Other mechanisms, such as development of maintenance contracts with manufacturers or distributors, should be ensured when possible. • Supply of standardized key equipment should be advocated to ensure availability of essential lab tests and to facilitate maintenance mechanisms for key equipment. Selection of key equipment should be rationalized according to principles of suitability for Rwandan conditions, availability of technical capacity to operate them, and feasibility of providing maintenance services. • Budget for equipment maintenance should be allocated at each health facility.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
LABORATORY SUPPLY MANAGEMENT SYSTEM		
Inventory management, availability of supplies, and management information systems • National list of essential laboratory supplies and reagents exists and has been defined by different levels of the health system. • Laboratory managers are heavily involved in quantifying and ordering products for the laboratory. • Some basic procedures for recording and storing information are in place and are being discussed for the national lab policy.	**Inventory management, availability of supplies, and management information systems** • The national list of essential lab supplies does not include ART-related lab commodities. • Shortages of supplies and stock-outs were among the top four obstacles to HIV-related lab work (reported by 46% of the facilities). A number of labs do not have the basic reagents for performing tests required for facilities at their level of the health system. The assessment showed that almost half of labs experience stock-outs of HIV test kits, reagents, and consumables within the last six months. • Procedures for recording and storing information are often insufficient and not standardized among laboratories. Information kept is not standardized and often is not complete enough to generate information for planning (for example for ordering of supplies). • Measures to guarantee confidentiality of lab records are not always in place. • Lab request forms are not standardized and in many cases are used only for certain tests. • Lab report forms are inadequately used.	**Inventory management, availability of supplies, and management information systems** • Essential lists for lab supplies (reagents, consumables, and equipment) should be developed for each level of health facility, including ART-related laboratory commodities. These lists should be congruent with the minimum packages of tests for health facilities (see Policies and Standards). • National guidelines for accepting donations of laboratory equipment, reagents, and supplies should be developed and adequate communication channels with donors advocated in order to enhance coordination and responsiveness to needs. • Availability of essential supplies should be supported by introducing appropriate quantification mechanisms for laboratories and suppliers. Budgets should be reviewed according to quantification updates. • Standardized procedures and forms for ordering, recording, registering, and storing information that ensure patient confidentiality should be established at central level and implemented at facility levels. The use of selected existing forms is recommended as a practical tool.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
	• Inventory management seems to be inadequate because expired reagents were found in 42% of the labs. • Policies regarding expired products and disposal are not available. • Information gathered from laboratories in the national health management information system is not being fed back to peripheral labs for performance improvement. • It is not clear to what extent the Rwandan Ministry of Health uses information generated by laboratories in Rwanda for planning and allocating resources. Flow of information within the national laboratory system is unclear.	• Standardized monthly reports should be prepared at each laboratory with key information on laboratory operations such as number of tests performed by each category. • Standardized inventory management tools and practices should be developed at central level and established in all laboratories, including those for control and disposal of expired items. Six monthly reports are recommended for key reagents and supplies. • An indicator-based monitoring system should be developed for key laboratory supplies at the national reference laboratory. • An indicator-based monitoring system for availability of key reagents and test kits for the ART program should be established. • A communication system within peripheral facilities should be established. Mechanisms and regulations that allow supply transfer among laboratories should be established. • A communication system between peripheral and referral laboratories should be established. Feedback from supervisory visits should be ensured and accompanied by technical support to improve performance. • Monthly and six-monthly reports should flow to and from peripheral labs to district health authorities for compilation and analysis before being forwarded to the national reference laboratory.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
Quality assurance/quality control • A few labs have internal and external quality control systems—at referral and district level and mostly geared to vertical programs.	**Quality assurance/quality control** • A number of labs had no standard procedures for handling specimens, recording information, and disposing of waste. • Some labs were not using universal precautions (gloves) at the time of the assessment. • Only 6 laboratories out of 37 surveyed had postexposure prophylaxis policies and procedures. • Few labs have a system of internal qualitycontrols, and most quality assessment seems to be focused on testing vertical programs such as TB and VCT.	**Quality assurance/quality control** • On-site technical support and adequate training should be provided to all laboratory and clinical staff at all levels of the health system to improve and ensure quality assurance and quality control in the following areas: o Specimen collection and handling guidelines o Use of forms and information management o Training in universal precautions o Postexposure prophylaxis • An indicator-based checklist with key elements of quality control and quality assurance should be developed and used by the national reference laboratory for supervising peripheral laboratories. • Communication mechanisms between supervisory structures and peripheral levels should be established to ensure feedback and technical support for improved performance. • Quality control records should be standardized and kept in the laboratory, and monthly reports should be conducted on quality control activities.
Referral system • A referral system has been defined at the national level. • An informal referral mechanism exists. Patients are being referred for certain tests related to ART, albeit informally. Such tests include CD4, viral load, and	**Referral system** • The national referral level has not been implemented efficiently. • Horizontal referral, that is, referring specimens within the same level of the health system, is a common practice performed when tests are unavailable, which sometimes overloads the	**Referral system** • Referral systems and procedures for specimens and patients should be established at each level of health care. • A recording and reporting system should be established to support referral procedures.

STRENGTHS/OPPORTUNITIES	LIMITATIONS	RECOMMENDATIONS
biochemistry. **Financing** • Laboratory budget exists at the national level. • Patients already pay for certain lab tests. • A number of labs use revenues generated by lab tests to replenish lab supplies.	referral labs. • Vertical referral between levels of the health system seems not to follow standard procedures. **Financing** • Inadequacy of laboratory budget was identified as a problem by referral laboratories. • Some institutions waive fees for a large number of patients found to be indigent.	**Financing** • Budgets should be reviewed according to current activities, level of health care, and expected increase in range of tests. • Effectiveness of cost-recovery mechanisms should be reviewed. Further investigation is needed in order to understand the percentage of fees that are being waived and to what extent existing fees reflect costs. • Allocation of national budget for lab should be reviewed. • Allocation of lab budgets at individual health facilities should be reviewed.

ANNEX 1. SAMPLING OF PUBLIC AND MISSION HEALTH FACILITIES

Province	Health Facility	Level of Care					Ownership		Services Provided					
		RH	DP	DH	HC	DIS	PU	AG	ARV	IO	STI	PMTCT	TB	VCT
NATIONAL	CAMERWA							1						
NATIONAL	BUFMAR							1						
NATIONAL	NAT LABORATORY						1							
NATIONAL	TRANSFUSION SANGUINE						1							
KIG VILLE	BIRYOGO				1			1	1			1		1
KIG VILLE	CENTRE HOSPITALIER KIGALI	1					1		1			1		
KIG VILLE	KACYIRU				1		1		1			1		
KIG VILLE	GITEGA				1		1		1			1		
KIG VILLE	KICUKIRO				1		1		1			1		
KIG VILLE	MUHIMA			1			1		1					1
KIG VILLE	HOPITAL MILITAIRE DE KANOMBE	1					1		1					1
KIG VILLE	KINYINYA				1		1					1		1
KIG NGALI	PHARMACIE DISTRICT BUGESERA		1				1							
KIG NGALI	NYAMATA			1				1						1
KIG NGALI	NYAMATA				1		1			1	1		1	
KIG NGALI	RUHUHA				1			1		1	1	1	1	1
KIG NGALI	PHARMACIE DISTRICT RULI		1				1							
KIG NGALI	RULI			1				1				1		1
KIG NGALI	RULI				1			1						
KIG NGALI	RWANKUBA				1			1		1	1	1	1	1
GITARAMA	PHARMACIE DISTRICT KABGAYI		1				1							
GITARAMA	GITARAMA				1		1					1		1
GITARAMA	KABGAYI			1				1				1		1

GITARAMA	PHARMACIE DISTRICT REMERA-RUKOMA		1				1							
GITARAMA	REMERA-RUKOMA			1				1						
GITARAMA	REMERA-RUKOMA				1			1						
GITARAMA	PHARMACIE DISTRICT GITWE		1				1							
GITARAMA	GITWE			1				1						1
GITARAMA	GITWE				1			1						
BUTARE	PHARMACIE DISTRICT KABUTARE		1				1							
BUTARE	BUTARE HOP UNIVERSIT	1					1		1			1		
BUTARE	KABUTARE					1	1							
BUTARE	PHARMACIE DISTRICT KIBIRIZI		1				1							
BUTARE	KIBILIZI			1			1							1
BUTARE	DISTRICT PHARMACIE NYANZA		1				1							
BUTARE	NYANZA			1			1							1
GIKONGORO	PHARMACIE DISTRICT KIGEME		1				1							
GIKONGORO	KIGEME			1				1				1		
CYANGUGU	PHARMACIE DISTRICT GIHUNDWE		1				1							
CYANGUGU	GIHUNDWE				1		1			1	1		1	1
CYANGUGU	PHARMACIE DISTRICT MIBILIZI		1				1							
CYANGUGU	MIBILIZI			1				1				1		
CYANGUGU	MUSHAKA				1			1		1	1	1	1	1
KIBUYE	PHARMACIE DISTRICT KIBUYE		1				1							
KIBUYE	KIBUYE			1			1					1		1
KIBUYE	PHARMACIE DISTRICT KIRINDA		1				1							
KIBUYE	KIRINDA			1				1						1
KIBUYE	PHARMACIE DISTRICT MURUNDA		1				1							
KIBUYE	MURUNDA			1				1		1	1	1	1	1

GISENYI	PHARMACIE DISTRICT GISENYI		1				1							
GISENYI	GISENYI			1			1			1	1	1	1	1
GISENYI	PHARMACIE DISTRICT KABAYA		1				1							
GISENYI	KABAYA			1			1					1		
RUHENGERI	PHARMACIE DISTRICT RUHENGERI		1				1							
RUHENGERI	RUHENGERI			1			1			1	1	1	1	1
BYUMBA	PHARMACIE DISTRICT BYUMBA		1				1							
BYUMBA	BYUMBA			1			1					1		1
BYUMBA	BYUMBA				1		1			1	1	1	1	
BYUMBA	MUHURA				1		1			1	1	1	1	1
UMUTARA	PHARMACIE DISTRICT NYAGATARE		1				1							
UMUTARA	NYAGATARE			1			1					1		1
KIBUNGO	PHARMACIE DISTRICT KIBUNGO		1				1							
KIBUNGO	KIBUNGO			1			1							1
	SAVE				1			1						
KIBUNGO	PHARMACIE DISTRICT RWAMAGANA		1				1							
KIBUNGO	RWAMAGANA			1			1			1	1	1	1	1
	TOTAL	**3**	**21**	**20**	**17**	**1**	**45**	**17**	**8**	**11**	**11**	**25**	**11**	**25**

ANNEX 2. DATA COLLECTORS TRAINING SCHEDULE

	PLACE	CONTENT	TRAINER	DATES
Phase 1				
1	BOARDROOM	Presentation MSH / RPM Plus Presentation goals and objectives survey Review of questionnaire Proposal to translate questionnaire into French	Chiel Lijdsman Vedaste Munyakindi	22-août-03
2	FIELD VISIT	Pretest questionnaire	Chiel Lijdsman Vedaste Munyakindi	24-août-03
3	BOARDROOM	Incorparate feedback from pilot site	Chiel Lijdsman	25-août-03
4	BOARDROOM	Training of teams	Chiel Lijdsman	1-sept.-03
5	BOARDROOM	Training of teams	Chiel Lijdsman	2-sept.-03
Phase 2				
1	BOARDROOM	Debriefing of field teams	Chiel Lijdsman Vedaste Munyakindi	3-sept.-03
2	BOARDROOM	Mid term survey follow-up	Chiel Lijdsman Vedaste Munyakindi	7-sept.-03

ANNEX 3. TRACER DRUG LIST

OUT-OF-STOCK FORM FOR TRACER DRUGS

STAFF TITLE _____ PU AGR PR

LEVEL HR DP DH CS

DATE _____

Number of days out of stock at facility or level <u>from distribution site</u>

General medicines	Jul-02	Aug-02	Sep-02	Oct-02	Nov-02	Dec-02	Jan-03	Feb-03	Mar-03	Apr-03	May-03	Jun-03	Total	Total
Aluminium hydroxyde 500 mg caps														
Amoxilline 250 mg caps														
Ampicilline 500 mg inj vial														
Co-trimoxazole 480 mg caps														
Water for injection 10 ml														
Glucose iso 5% 500 ml														
Metronidazole 250 mg caps														
Norfloxacine 400 mg caps														
Oral rehydration salts, sachet 27.5 g/L														
Paracetamol 500 mg caps														
Peni procaine 3+1mui flacon inj														
Penicilline V 250 mg caps														
Quinine 300 mg/ml amp inj 2 ml														
Quinine sulfate 300 mg caps														
Ringer's lactate flacon 500 ml														

Medicines - PNILT														
Rifampicin 300 mg caps														
Isoniazide 100 mg caps														
Rifam picin 120 mg / isoniazid 50 mg / pyrazinamide 300 mg														
Medical supplies														
Hypodermic needles UU 21 G														
Catheter, short IV UU 22 G														
Examination gloves NS UU 7.5														
Surgical gloves, sterile UU 7.5														
Gauze rolls, hydro 36 in x 100 yds														
Syringe UU Luer 5 ml														
IV kit S UU needle														
Other medicines														
Chlorhexedine 1.5% cetri 15% L														
Polyvidone iodine 10% 200 ml														

ANNEX 4. RECOMMENDED LABORATORY TESTS FOR MONITORING PATIENTS ON ART IN LOW-RESOURCE-SETTINGS

Absolute minimum tests			
Type of Test	**Purpose of Test**	**Level of Health System**	**Comment**
▪ HIV antibody test	**Baseline** test to **confirm** HIV infection	**HC, DH, RH**	Required to provide effective monitoring of most regimens
▪ Hemoglobin and Heamatocrit levels	**Baseline** test to screen for anemia before starting AZT-containing regimens **Monitoring** test after starting ARVs	**DH, PH**	
Basic recommended tests			
▪ White blood cell count and differential	**Baseline** and **monitoring** test to permit assessment of neutropenic side effects	**DH**	Are not absolutely essential but highly recommended to provide monitoring for safe use of drugs and to help doctors decide when/how to switch regimens Note: CD4 is not included because of expense, but may consider moving into this category as CD4 testing becomes cheaper and easier, since CD4 cell counts are the best indicator of immune response to treatment
▪ Total lymphocyte count	**Baseline** test to assess immune functioning (alongside CD4 count) and **monitoring** test to assess neutropenic side-effects of regimen	**DH**	
▪ Serum ALT or AST	**Baseline** test to assess for hepatitis coinfection and **monitoring** test for hepatotoxic side effects of ART regimen	**DH**	
▪ Serum creatinine	To assess baseline renal function	**DH**	
▪ Blood urea nitrogen	To assess baseline renal function	**DH**	
▪ Serum glucose	**Baseline** to assess for diabetes before starting ART, and test to **monitor** for hyperglycemia after initiating ART	**DH**	
▪ Pregnancy tests	**Baseline** to determine most suitable ART regimen	**DH**	

Desirable tests			
Type of Test	**Purpose of Test**	**Level of Health System**	**Comment**
▪ Bilirubin	**Baseline** to assess for underlying liver abnormalities and monitoring test to check for development of liver problems with certain ARV regimens	**DH**	"Provide significant information that would be beneficial in the monitoring of ARV use in resource-limited settings"
▪ Serum amylase	**Baseline** test to assess for hepatitis co-infection and **monitoring** test for hepatotoxic side effects of ART regimen	**DH**	
▪ Serum lipids (lipid profile) ➢ Cholesterol ➢ Triglycerides ➢ High-density lipoproteins ➢ Low-density lipoproteins	**Baseline test** to indirectly examine baseline liver function. **Monitoring test** to monitor for hepatoxicity with PI-based regimens	Not mentioned	
▪ CD4 count	**Baseline to** assess functioning of the immune system prior to starting ART, and to assess for effectiveness of therapy after beginning ART	**PH**	
Optional tests			
▪ Viral load	**Baseline test** to decide whether to initiate ART **Monitoring test** to see whether ART drug regimen is working	**PH**	
▪ Viral resistance	**Baseline test** to check for background resistance exists prior to initiating ART regimen and **monitoring test** to see if suspected resistance to ART develops	**Regional referral center**	Viral resistance does not figure into WHO's classification

Additional tests included in ART protocols in low-resource settings[40]			
Type of Test	**Purpose of Test**	**Level of Health System**	**Comment**
▪ Anion gap (calculation derived from electroyte values)	**Monitoring** for electrolyte imbalance associated with ART regimens that can cause lactic acidosis	No recommendations available	
▪ Serum lactate	**Monitoring** for lactic acidosis	No recommendations available	
▪ Creatinine phosphokinase	**Monitoring** for development of pancreatitis	No recommendations available	
▪ Chest X-ray for TB	**For diagnosis or confirmation** of tuberculosis or *pneumocystis carinii* pneumonia (PCP)	No recommendations available	

[40] These tests are included in the protocol for the USAID-funded Mombasa ART Program.

ANNEX 5. LABORATORY TESTS TO BE PROVIDED AT EACH LEVEL OF THE RWANDA HEALTH SYSTEM

Health Center			
Hematology	***Microbiology***	***Urinalysis***	***Microbiology/Parasitology***
• Hemoglobin	• Acid-fast bacillus sputum smears for TB detection	• Albumin • Sugars	• Thick blood film • Thin blood smear • Stool exam for ova and parasites • Urine sediment for schistosomiasis and cytology

District hospitals will be expected to provide the minimum package described above plus a complementary package of activities as summarized in the following table.

District Hospital Laboratory				
Hematology	***Microbiology***	***Urinalysis***	***Parasitology***	***Biochemistry***
• Hemoglobin • Hematocrit • White blood cell counts and differentials • Coagulation time • Blood grouping • Erythrocyte sedimentation rate	• Acid-fast bacillus sputum smears for TB detection • Urine sediment • Gram staining	• Albumin • Sugars	• Thick blood film • Thin blood smear • Stool exam for ova and parasites • Urine sediment for schisto-somiasis and cytology	• Blood glucose • Urea and electrolytes • Uric acid • Creatinine • ALT • AST

ANNEX 6. DISTRIBUTION OF LABORATORY STAFF BY LEVELOF THE HEALTH SYSTEM

Level	AO	A1	A2	A3	Trained On-Site	Other	Total
Referral-level facilities							
National Reference Laboratory	2	6	11	0	0	2 persons with M.Sc in lab sciences 1 physician 1 financial administrator 1 accountant (A1) 3 drivers 3 cleaners	30
Centre Hospitalier Universitaire de Kigali	2	2	18	4	4	1 medical microbiologist	31
Kanombe Military Referral Hospital	1	3	7	2		5 cleaners	18
Butare University Hospital	1	7	18	2	2	2 physicians 23 support and administrative staff	57
Total	6	18	54	8	6	42	136
District hospital laboratories							
Nyamata			2				2
Ruli			3	1	1	1 lab assistant	6
Kabgayi			5	1		1 worker	2
Remera-Rukoma			2		2		4
Gitwe		1	2			1-A2 nurse	4
Nyanza			3	1	1		5
Kigeme			3	1		1 worker	5
Mibilizi		1	1	1			3
Kibuye			2				2
Murunda			2				2
Mugonero		1	1				2
Gisenye		1	3			1 nurse, 1 health assistant 1 biochemist	7
Kabaya			2				2
Ruhengeri		1	7		2		10
Byumba		1	1	1			3
Nyagatare			2		2		4
Kibungo		1	2	1			4
Rwamagana		1			3		4
Total	0	8	43	7	11	7	74

Level	AO	A1	A2	A3	Trained On-Site	Other	Total
Health center laboratories							
Kabaya			1				1
Nyamata				1		1 lab assistant	2
Save					2		2
Bilyogo			2	1	5		8
Ruhuha			2				2
Kabgayi			2	1	1		4
Mushaka				1	1		2
Gitega			3			1 health assistant	4
Rwankuba			1			1 lab assistant	2
Muhura			1	1	1		3
Kacyiru			3			2	5
Kinyina			1			1 health assistant	2
Gitwe				1			1
Gihundwe			2		1	1 worker worker	4
Kicukiro		1	5				6
Total	0	1	23	6	11	7	41

ANNEX 7. INVENTORY OF ESSENTIAL LABORATORY SUPPLIES AND EQUIPMENT[41]

DISTRICT-LEVEL LABORATORY
VCT/PMTCT (Rapid testing protocol for HIV diagnosis)
Disinfectant
Medical wipes
Blood lancets, sterile, stainless steel, single use
Capillary tubes
Sharps container, disposable, 6-L capacity
Biohazard disposal bags
Determine HIV1/2 test kits (Abbott Laboratories)
Unigold HIV1/2 test kits
Capillus HIV-1/HIV-2 (Trinity Biotech) test kits
Reagents for Determine HIV1/2
Reagents for Unigold HIV1/2
Reagents for Capillus HIV1/2
Blotting paper
Ziploc bags with dessicant
ELISA reader, washer, printer, and accesories
Distillation unit and accessories
ELISA test kit (provide name)
Incubator/water bath
Centrifuge
Reagents
Refrigerator
Agitator, rocker, tray mixer
Aspiration device
Measuring cylinders
Graduated pipettes, glass
Graduated pipettes, plastic
Single-channel micropipettes
Multichannel micropipettes
Disposable pipette tips
Dilution tubes/rack
Reagent troughs
Stop solution (sulfuric acid/sodium hydroxide)
Disinfectant
Gloves
Pipette aids
Absorbent paper

[41] This list was adapted from several lists, including the WHO/AFRO list of essential supplies for HIV testing.

Cotton wool
Spirit
Syringes (5 ml)
Needle (21 G)
Vacutainers (plain)
Vacutainers (EDTA)
Labels
Timer
Antenatal care/PMTCT
Microscope
Immersion oil
Clean glass slides
Glass rods
Sink or staining tank
Measuring cylinder (50 ml)
Wash bottle with buffered water
Interval clock timer
Rack for drying slides
Leishman stain, methanol
Field stain A
Field stain B
Microscope slides
Blood lancets
Cotton wool
Counting chamber
Pipette (0.05 ml)
Pipette (graduated, 1.0 ml)
Turk dilution solution
Tally counter
Hemaglobometer
Microhematocrit centrifuge (manual)
Microhematrocrit centrifuge (electric)
Scale (for reading hematocrit results)
Heparinized capillary tubes
Spirit lamp
Ethanol
Indicator papers and tablets
Test tubes
Rack
Measuring cylinder (10 ml)
Dropping pipette
Sodium nitroprusside
Calcium acetic acid

Ammonia
Pipette (5 ml)
Sulfosalicyclic acid (300 g/dl aqueous solution)
Lugol's iodine solution
Rapid plasma reagin test kit
Ehrlich's reagent
TPHA test kit
Hematology
Coulter® Ac.Tm 10
Coulter® MAXM
Ac Trone Cell Control
4C PLUS Cell Control
AcT Tainer
Isoton® III
Lyse S III
Coulter® PAK
Coulter® 5C Cell Control
Microscope, binocular, electric, Leitz
May-Grunwald solution
Giemsa stain solution
Buffer phosphate, pH 6.8
Immersion oil, refractive index 1.516
Sodium chloride, 0.9%
Ethanol 100%
Staining rack
Test tube rack
Hand tally counter 0–99
Partec CyFlow
FACScount
FACScan Multiset
FastImmune T lymphocyte value bundle
Reagents for CD4/CD8 testing
Biochemistry (in addition to items mentioned previously in the list)
Spectrophotometer
Autolab
Printer
Kit for creatinine
Kit for bilirubin
Kit for ALT
Kit for AST
Kit for urea and electrolytes
Kit for glucose
Kit for amylase

Centrifuge
Incubator
Microbiology (in addition to items mentioned previously in the list)
Culture media
Additives for culture media
Antibiotic discs

GENERAL LABORATORY USE

Latex gloves
Heavy-duty gloves
Lab coats
Plastic aprons
Chest freezer (- 30 C)
Biohazard labels
Autoclave
Incubator
Hot air oven
Water bath
Centrifuge
Transport box, polystyrene
Specimen mailing box
Cryobox
Markers
Cool boxes
Ice packs
Refrigerator thermometer
Sodium hypochlorite granules, 70% chlorine
Phosphate-buffered saline
Sulfuric acid 96%
Sodium hydroxide
Fetal calf serum